UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE:	)	2:12-md-02342-CMR
	)	
ZOLOFT (SERTRALINE HYDROCHLORIDE) PRODUCTS	)	September 1, 2015
LIABILITY LITIGATION	)	10:34 a.m.-3:27 p.m.
J. RETTENMAIER USA LP	)	Philadelphia, PA

DAUBERT HEARING
BEFORE THE HONORABLE CYNTHIA M. RUFE

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P R O C E E D I N G S

THE CLERK: All rise.

(Call to Court)

THE COURT: Good morning, everyone.

ALL: Good morning, Your Honor.

THE COURT: Please be seated. I see the courtroom is ready for the Daubert hearings that we continued to today. I would like to address two matters prior to us hearing statements --

UNIDENTIFIED: Your Honor, I just want to apologize in advance. Two of our members, Brian Alstruck (ph) and his partner, Jace Smith (ph) were held up at the airport, they'll be late, but they'll be here.

THE COURT: Do you need them to start?

UNIDENTIFIED: No.

THE COURT: Counsel, there are some matters to address before we actually get on with the hearing, which I hope will be any moment now.

Is there somebody on the phone?

UNIDENTIFIED: No, I was checking it.

THE COURT: All right. That's one.

UNIDENTIFIED: (indiscernible) by Mr. Zonies.

MR. ZONIES: It wasn't me, I swear.

THE COURT: All right. Let me clarify. Is there any pending Daubert issue related to Robert Gibbens (ph)? I thought it was resolved, I just want this here on the record.

MR. CHEFFO: Our understanding is it's been resolved, Your Honor.

MR. ZONIES: Your Honor, our understanding is that Dr. Gibbens has been pulled down as an expert and therefore the Daubert motion would be moot or Your Honor just could grant it, which we'd be happy with as well, but assuming it's --

THE COURT: Then there won't be any testimony on Mr. Gibbens' report.

Then putting that aside, I would like to address the motion that was filed to de-designate documents, and I wanted to give each side a brief opportunity to address it. There are voluminous papers filed here, and many, many, many documents attached to those.

And I understand that when a motion to de-designate documents that have been labeled confidential under our system in the MDL, the PTO No. 8 would control, but that is subject to evaluation and analysis.

The burden would be on the party that

has declared certain documents or evidence to be confidential to show why it is so, and as far as I can read, there's no claim of attorney/client privilege or work product.

So we're talking about a number of e-mails, many of which are hearsay, and they would never make it into evidence. So I'm wondering why I have to deal with that at all.

Those are accompanied by some that are not at issue. Dr. Kimmel (ph) and the study authors and Sandra Greenfield and Luac (ph) study authors, they are not at issue. So we're really talking about a smaller subset. And I'd like to know if this is still an issue between the parties, because otherwise ruling en masse to all the e-mails that may be at issue seems to me superfluous, unnecessary and if it's not going to be admissible in this litigation, then it's also moot.

So, Mr. Cheffo, you filed the motion.

MR. CHEFFO: Yes, Your Honor. Just let me say this, and I'll try to address all those questions.

First I would say for the purposes of this hearing, it shouldn't impact. That was from our perspective. So in other words, you know, to the

extent -- this isn't something that we think Your Honor has to make kind of a snap decision or rule on with respect to these issues.

Basically our argument, and I don't think that there's that many documents here, all right, so we haven't looked at this as kind of an en masse approach.

Really what happened was, you'll recall from the last hearing, the plaintiffs seem to take some issue with respect to certain contacts with study authors that resulted from Dr. Kimmel, you know, basically told the Luac authors, I am a consultant for the plaintiffs, we have that information, we've given that e-mail.

We then essentially said, you know, goose/gander rule, you know, have you had contacts with respect to the experts and the plaintiffs then produced that information to us. And our view is, when we provided those communications between Dr. Kimmel and others to the extent that they were there, including I think there may have been a lawyer request to certain experts for information. We just produced that information without labeling it confidential.

So quite simply our kind of view is we didn't see the distinction. These were -- there was

no work product, there was no privileged claim. These were e-mails that were sent to either consulting experts or non-parties or folks who may have been retained and they addressed specifically the issues here.

So the plaintiffs having asked for this information, in fact, subpoenaed most of these documents. They were the ones who issued the subpoena to Boston University for the Luac documents. They then produced them, and we basically just said, it was not clear to us as to -- if there was no privilege, no work product, why these would be confidential. And they are frankly a very limited number of documents, and they're only the documents that were really produced following the last hearing.

So that's really what this is about. Now, to the extent that they may have issues in terms of hearsay or admissibility, you know, that's certainly a fair point in terms of the trial. But, of course, as Your Honor knows, it depends on how things can be used, experts can often rely on issues of hearsay that may not otherwise pass muster on certain of the evidentiary rules.

These are all issues that Your Honor will certainly address if and when we ever get to a

trial, and we appreciate that. And that's frankly true for, you know, probably a lot of the millions of documents that both sides have produced.

So I guess in sum, we have not taken -- we don't think or didn't mean to take kind of scattered shot or shotgun approach to it because there is a goose/gander rule. We're not trying to get into documents that we think were legitimately characterized as confidential. These are documents that really we didn't understand what the basis would be, because no privilege, no work product, third parties. These are folks who really there was no expectation of confidentiality or privacy.

THE COURT: All right. Thank you. And I will ask for the PSE's response. Mr. Robinson.

MR. ROBINSON: Good morning, Your Honor.

THE COURT: Good morning.

MR. ROBINSON: You know, I agree, Your Honor, with Mr. Cheffo, that I think if at all, there's just a few documents that may be work product, and I think we need to argue that with you under your PTO. But I don't -- I think at this point -- now, if a document came into evidence and was allotted evidence then obviously it would not be protected.

But there was a similar motion made by the defense on documents that they said was -- they gave it to us, but they said they were confidential. And I think it was RR-8, No. 8, report and recommendation No. 8.

THE COURT: Right.

MR. ROBINSON: The Court ruled that --

THE COURT: Affirmed without objection by PTO-8.

MR. ROBINSON: Yes, Your Honor. And so we're basically at this point objecting to some documents, and we've laid it out in our brief, but I do think that it's something we can talk to Mr. Cheffo about and it's something we can do later.

THE COURT: If it comes up in this litigation, I think -- I'll take that right now and put together what each counsel are telling me, that it isn't all of the e-mails you had me review. It is a few that may be relevant to some and admissible pursuant to some Federal Rule of Evidence. And I would prefer to take those few as they arise, rule on them in the context of confidentiality as well as pursuant to PTO-8 as well as admissibility in this proceeding. And I'm not thinking about a trial, I'm thinking about this proceeding.

And until I hear the context, it may or may not be permitted. And I would prefer to do it that way instead of ruling en masse that this is or is not like the ruling we made previously concerning Pfizer's internal e-mails, which were not part of the litigation. That's how we ruled, there was no objection to it.

So let's see where this goes, but there are so many, what I consider to be superfluous and also a side trial and a side hearing, and while they're interesting, I don't think they belong here. I don't think they'll get into evidence.

So you decide what you really want to use, each side, and we will address that as it comes up in this hearing this week. And then I'll rule on those. But I won't rule, Mr. Cheffo, on your motion en masse.

MR. CHEFFO: Understood, Your Honor.

THE COURT: Because there's too many e-mails on each side that are presented. And while you've asked for those, in reference to Dr. Brerard (ph) and Shae Shaver (ph) and Dr. Jewell primarily, and between Dr. Jewell and study authors, Huberts (ph) and Luac, and I think the third category was Shaver and study authors Jiminea Solom and Hubrix (ph), we'll

address those as they become relevant. All right? And we'll leave that there, and let's go on with the actual hearing and testimony.

Do you need to make an opening statement?

MR. CHEFFO: Yes, Your Honor, I would like to do that.

THE COURT: Proceed.

MR. CHEFFO: Thank you. I have a few extra copies of the slides. I'll give one actually to you.

THE COURT: I made space.

MR. CHEFFO: So just before I do start, there may be a document or two in this presentation, I guess because the opening is not technically evidence, we can -- you know, however Your Honor wants to deal with it, defer on those documents ultimately --

THE COURT: Defer, please.

MR. CHEFFO: -- later about whether you want, but there's not a lot of them, but I may be referencing one or two of those documents.

THE COURT: All right.

MR. CHEFFO: Well, with that, Your Honor, thank you very much as always for providing us with the time to address these important issues. I'm

going to be presenting the opening statement for Pfizer. You'll recall Pam Yates, Ms. Yates and I will be conducting the hearing with as usual a little help from our friends.

This is not the first Daubert hearing in this MDL. As Your Honor knows, we had a 7-day Daubert hearing last April it was, and the Court excluded Dr. Brerard's opinions in their entirety because she used novel and unreliable methods.

Plaintiffs then, as Your Honor will recall, moved for reconsideration. They argued that the decision was contrary to the Supreme Court and Third Circuit precedent, and Your Honor gave both parties -- both sides a full and fair opportunity to address those issues and deny the reconsideration motion and reaffirmed the decision with respect to Dr. Brerard.

After that, Plaintiffs moved to allow them to replace Dr. Brerard with Dr. Jewell, and they told the Court a number of things. They said Dr. Jewell applied different methodology than Dr. Brerard. That they were focused only on cardiac birth defects, and they suggested at the time that the science was changing substantially in plaintiff's favor, and we'll talk about that today.

We believe, Your Honor, that Dr. Jewell's testimony fairs no better than Dr. Brerard. His opinion said all cardiac defects are caused by -- can be caused by Zoloft or plagued by a constellation of mythological errors including many of the same errors and flaws that Your Honor identified with respect to Dr. Brerard.

Moreover, since -- and I think you'll see today, since last year's Daubert hearing, since that April hearing, the science has become even stronger in demonstrating a lack of causal relationship between Zoloft and birth defects.

And what was true then is true now, which is that there is no regulatory agency, there is no professional organization, no peer review treatise or no study that has concluded that Zoloft causes cardiac birth defects. The only people who make that claim are plaintiff's counsel and their experts.

Now, let me give the Court a little bit of a road map. The first issue that we will address and there's going to be five main topics, is the new science since last year's Daubert hearing. There have been no replicated, statistically significant associations of cardiac defects with Zoloft. That's the kind of headline.

The second topic is Dr. Jewell's lack of qualifications to offer a causation opinion here. As Your Honor certainly knows well, Dr. Jewell is a statistician, he's qualified to crunch numbers and deal with those issues. Our challenge here is his causation opinions. He's not a medical doctor, he didn't consult with an expert in cardiology in forming his opinions.

The third topic we're going to be dealing with is Dr. Jewell's improper application of the generally accepted methods and what we believe is a torturing of the existing peer review data. And he opines only on cardiovascular birth defects overall. There's no recognition of the heterogeneity between cardiac defects.

He disregards the requirements as you'll see for replication, he improperly relies on non-significant trends, he fails to account for confounding, and he conducts what we believe is a litigation re-analysis of peer reviewed accepted epidemiological data.

The fourth topic is situational science. That's essentially taking different approaches and applying different methodologies depending on a required outcome, even in situations

where one would expect an expert to follow the same methodology, and you're going to see that with respect to some of the approaches that Dr. Jewell has taken here and in the Prozac litigation.

And you'll see why the plaintiffs fought so hard to keep us and Your Honor from seeing his report in the Prozac litigation.

And finally the fifth topic is really a cherry picking and misrepresentation of Pfizer Company documents and we're going to hope to do is putting context and certainly give Your Honor a complete picture of the documents that Dr. Jewell has referenced in his report.

Now, we know that Your Honor, perhaps more than many courts is fully aware of Daubert and the Daubert standard, so I'm going to spend this much time talking about the law and Daubert issues.

The only thing I would highlight are really two I think principles or concepts from the case law. This is from the Third Circuit, the Paoli case. Any step that renders an expert's analysis unreliable renders the expert's testimony inadmissible, and where an expert completely changes or misapplies the correct methodology his testimony is inadmissible.

And also while general acceptance, we realize and recognize it's not a required kind of foundational or fundamental aspect of Daubert, it remains an important consideration under Daubert and we know that from the Daubert decision itself.

The theory that has been able to attract only minimal support within the community may properly be viewed with skepticism.

So this next chart is really where we left off, and many of those names I'm sure will be very familiar to Your Honor. And here, the data then as it does now, did not demonstrate that Zoloft is the cause of cardiac birth defects.

The scientific medical community then and now agree that a causal relationship did not exist between Zoloft and birth defects. So let's just highlight a little bit where we were very briefly back prior to the last hearing.

Your Honor will recall OTIS, which is the Organization of Teratology Information Specialists, OTIS determined that the available information does not suggest that Zoloft increases the risks for birth defects above the background rate. The Lorenzo peer reviewed published paper, there's no evidence that Zoloft increases the risk of major

malformations.

Miles, a particular important meta-analysis that we'll talk about today and I think throughout this hearing, Zoloft is not significantly associated with congenital malformations.

But since last year's Daubert hearing, there's been perhaps even a surprising and overwhelming amount of information and science that's become available, and it's become stronger in essentially ratifying all of those determinations and all of those findings from 2007 on.

You can see on the right-hand side, what we've put in kind of blue and black, that's just the new kind of science and position statements that have come out since Your Honor's last hearing. And what you'll see is that there are no replicates statistically significant associations of cardiac defects with Zoloft. We would expect to see that if there were.

Now, just to take a second on this, there's only so many organizations that we can't all fit them on the slide here. This is just since the last Daubert hearing. And these are the consensus. The scientific consensus with essentially Dr. Jewell on one side, and all of these organizations looking,

trying to find the answers with respect to these specific and very important issues, and Dr. Jewell clearly stands alone in contrast to these organizations.

Now, let's talk about the new data. So Bond, they reported no statistically significant association or cardiac defects with Zoloft. The evidence to disfavor certain SSRIs regarding teratogenicity remains weak and they all seem largely safe.

American Heart Association, it issued a scientific statement in 2014, in which it concluded that there is no increased risk to congenital heart defects associated with the use of most SSRIs. It did say although Paxil, not Zoloft, may be an exception.

And we have Hibrex (ph). Hibrex is a really important study for a number of reasons. First of all, it's Harvard researchers published in the New England Journal of Medicine, very recent, and it's a massive study, the largest study done to date, almost 950,000 women of which 14,000 were exposed to Zoloft.

These authors developed a three step process to control by indication, as Your Honor is probably aware. These processes and these steps are not done after people know the data. They kind of had

an approach, they formulate it, and then they applied that once they had the information.

And also, you know, certainly as Your Honor has seen through this and probably other hearings, early studies and early information important, no one is suggesting that we shouldn't look at them. But as studies develop we know that often they become more powered, and what happens is study authors like the Hibrex authors, like the Jiminea Solom authors try to identify what were perhaps weaknesses or shortcomings in prior literature, so they can design and devise studies and -- with a methodology to address these issues.

And that's what the Hibrex folks did. And what did they find? They found no statistically significant associations between Zoloft and any cardiac malformation, right ventricular outflow track obstruction, VSD or other cardiac defects.

They found that there's no significantly increased risks were observed with respect to specific cardiac defects previously, and this is important, hypothesized, previously hypothesized, not proven to be associated with SSRIs.

The authors concluded that their results suggest that the use of anti-depressants

during the first trimester does not substantively increase the risk of specific cardiac defects. The accumulated evidence implies low absolute risk and argues against important cardiac or teratogenic effects, associated with the most commonly used anti-depressant medications.

And, of course, this conclusion is absolutely inconsistent with Dr. Jewell's opinions here and his methodology with respect to causation. And it's for that reason, as you'll see, and as you have seen in Dr. Jewell's reports that he goes to such great lengths to contort and to kind of rejigger and to try and take this information and put a square peg in a round hole, because without that, there is no answer for a study that is published in the New England Journal of Medicine with almost a million women with 14,000 who find no association between Zoloft and cardiac birth defects.

But that's not the end of the story either, because then we have McDunna (ph) which is another peer reviewed meta-analysis and it was prepared for an agency that is part of the United States Department of Health and Human Services.

The McDunna meta-analysis reported actually a reduced risk of cardiac defects with

Zoloft. The authors concluded that the best evidence points to the fact that there's no increased risk of cardiac defects.

Then we have the APA, American Psychiatric Association, and American College of Obstetricians and Cardiologists. And this may look familiar and it is, because there was a 2009 statement that obviously predated the last Daubert hearing. But in 2014, ACOC reaffirmed their statement that the current data on SSRI exposure show no consistent information to support specific morphological teratogenic risks.

And the story continues with Otis (ph). Otis also reaffirmed its prior statement. Overall, the available information does not suggest that Zoloft increases the risks for birth defects above the background risk.

There's another meta-analysis, this is the Wang 2015 and it's published from the Journal of the American Heart Association. It reported no statistically significant association of cardiac defects from Zoloft, in fact, it reported odds ratio of 1:0, as Your Honor knows means that there is no association. And the authors concluded that SSRIs were not associated with cardiac defects.

Then there's Fooroo (ph) which is a 2015 study. When plaintiffs sought to -- permission from Your Honor to replace Dr. Brerard with Dr. Jewell, they argued, as I indicated, that the Court -- one of the reasons why Your Honor should allow them to do is because the science was changing in their favor, and the primary, at least first kind of support was, that they had characterized was the abstract from Fooroo.

Now, we believe they may have taken some license with that, but nonetheless, they made a big deal about Fooroo.

But ultimately the study was published. And this is another massive international study on Zoloft and birth defects. There were 7,245 women, that's just exposed to Zoloft, and it combined data from Denmark, Finland, Iceland, Norway, Sweden to look at birth defects, and particularly to look at cardiac defects.

And it was a very sophisticated sibling controlled analysis to adjust for confounding. One of the factors of the things they did, was to look at women who had multiple births children, that while they were taking an SSRI and while they were not, that was a component of this kind of complicated controlled

analysis.

And what did they find in this published peer review article looking at 7,000 women on Zoloft, no statistically significant association between Zoloft and any cardiac defect, kind of trample (ph) and major arch anomalies, atrial and ventricular septal defects, atrial, ventricular septal defects, right ventricular outflow tract obstructions and left ventricular outflow tract obstructions.

What did they conclude? Taken together, the results from our co-varied adjust analysis and the sibling controlled analysis point against a substantial teratogenic effect.

It's rare, Your Honor, that you see one or two or three studies, but to see this kind of crushing amount of data all pointing in one direction is unique, at least in many of the litigations that I've been involved in. And plaintiffs somewhat ironically ignore this peer review study in their briefs, although they had spent a lot of time talking about it when they believed the abstract was supportive of them.

Then there's another study that came out in 2015, I may be butchering the name, but I think is Wemocker (ph) or Wemaker (ph) and this study

reported no statistically significant associations between Zoloft and congenital heart defects, septal ASD/DSD to torology (ph) of flow, transposition of the grade vessels, ABSD, hyperplastic left heart cortication of the aorta and pulmonary valve stenosis.

Unlike many of the others, this study didn't adjust for factors such as depression, smoking, age, and medication use. It did have a finding for severe cardiac defects in this particular study, but it was based only in six findings, and of course, it lumped many of these heterogeneous defects together from four different cardiac developmental groups.

But perhaps most importantly for the Court's analysis, there's no replication of any of these findings for severe cardiac defects.

Then there is almost -- almost done with this, Your Honor. There's another study from the CDC 2015 and this was published in the British Medical Journal, a very well respected journal, and Zoloft was the most commonly used SSRI in the CDC study, which combined results from prior studies. The CDC finds no statistically significant associations between Zoloft and septal defects.

Now, there are two studies or two issues that are probably in this timeline that I left

out that I'm going to talk about, but they require just a tad more explanation. One actually I think both you'll be familiar with.

The first is Luac, the 2007 study and Your Honor knows that there has been a very important and significant development with respect to the Luac 2007 studies, and what appeared to be a positive finding in that study for septal defects with respect to Zoloft.

And, of course, this development and this issue was significant, if not a major role as to why Your Honor afforded the parties an opportunity to come back today, as opposed as to the hearing in July.

Now, last year at the Daubert hearing with Dr. Brerard, Pfizer acknowledged that there were two independent studies that reported a significantly -- a statistically significant association for Zoloft and septal defects. Those were the only two.

And one of the studies that because it was peer reviewed and published, was Luac. And as the Court kind of recognized, Luac reported a statistically significant association between Zoloft and septal defects. We now know that that was incorrect, that was not right. We now know and I should add that this has now been published, and this

is both on-line and in their written journal.

The correct confidence interval is 1.0 to 4.0. So there are no replicated findings for septal defects. And just kind of as a footnote, one of the issues that I think you may see or hear about, both -- from both sides, is whether 1.0 is really 1.0 or whether it's 1.0000, .1, it's statistically significant, I think you'll see from -- and that's why these doctors are particularly important.

That 1.0 is actually I think .96 rounded up. So there is no question that the actual data, the actual information runs from 1.0 to 4.0 which means unequivocally that it is not statistically significant.

And you'll see from the documents that it's not just us saying that, this is exactly what the journal authors and editors required with respect to their correction. And frankly the authors didn't disagree with that.

So plaintiffs recognized that this was very significant, and they actually asked two of their experts to contact the Luac study authors about the correction. And this is -- I think this is actually from the day before the last hearing, either that or the same day, Dr. Jewell tells the authors that he

would be interested in seeing the statistical analysis output that led to their correction.

Second, plaintiffs asked their consulting expert, there's -- in one of the e-mails he identifies himself I think as kind of working with Mr. Robinson to contact the study, the Luac study authors as well, so there's kind of dual efforts by the plaintiffs to try and understand or get some more information.

As Dr. Greenland writes here, in light of the correction, the big question, he says, is what's the second digit past the decimal point for the lower bound of the confidence interval.

So why is it that the plaintiffs are so interested in finding out this data. Well, if the lower bound of the confidence interval was nominally above 1, as I said say 1.01 then plaintiffs would argue that the finding is still statistically significant.

Now, we know though from the e-mails that the plaintiffs actually subpoenaed from the Luac study authors that Dr. Luac herself said the confidence interval, the lower bound is .982. Which means that it's less than 1, it's only been rounded up, so we've answered that question.

We also know that the e-mails that plaintiffs subpoenaed, that the New England Journal -- from the plaintiff's subpoenaed documents, the New England Journal recognizes the importance of statistical significance.

An editor from the Journal recognized that confidence integrals that include one (indiscernible) usual criteria are statistically significant.

The Journal required the study authors to remove an emphasis on findings that are not statistically significant. Drs. Mitchell and Luac acknowledged the Journal's position, and accepted the Journal's revision that removed the emphasis on the non-statistically significant findings for Zoloft and septal defects.

And, of course, this determination, this information, this approach is 100 percent consistent with Your Honor's rulings with respect to statistical significance with respect to Dr. Brerard.

And speaking of Dr. Brerard, let's talk about a recent publication from Dr. Brerard. Now, this -- she published a paper in 2015, and there's a few things of note. The first is she finds no statistically significant associations for any end

points with Zoloft, including cardiac malformations except she finds two positive findings. One for VSD/ASD and the other for cranial stenosis, which Your Honor knows is not even at issue here, because those cases have now all been dismissed.

But even as to these two positive findings, it seems that Dr. Brerard has made another very significant mistake in charting her data. In her crew data for VSD and ASD, Dr. Brerard reported an odds ratio of 1.35, with a confidence interval of 1.01 to 1.79.

Now, something didn't look right in this information, so Dr. Kimmel went to something called open epi (ph). You and I could do it if we were so inclined, it's kind of a computer program that's open, and you kind of punch in the numbers, and when you punched in the numbers, said well, this is not, this is using the crude data, this is not statistically significant, this doesn't seem right.

So then what he did was he went and he said, well, let me try the other positive finding. And again, he punched in the numbers, using the raw data that was provided by the study authors, and he said again, this is not the same. This is not statistically significant.

So just to be sure that maybe he wasn't missing something, he said, well, let me go and look at all of the findings, okay again, this is a -- a little bit of a busy chart, but essentially what it shows is that he checked -- sorry about that, Judge, he checked every one of the findings, and they all kind of squared out, they were all right.

The only ones that seemed to be wrong were the two positive findings. So, you know, kind of on our side of the V, Your Honor, we were scratching our heads, that doesn't seem right, and we've known that Dr. Brerard has had some issues with certain other calculations.

So we've now found that it's actually not just Pfizer, the lawyers, Dr. Kimmel who believes that there is some significant issues with respect to these two findings. But, in fact, we know that the PSE also agrees that there's something very, very wrong with those two positive findings.

So Your Honor knows that there was a Frye hearing before Judge Bernstein and the PSC -- PCCP, excuse me, that was in February. So this e-mail relates to some of the goings on with respect to that particular hearing.

It was brought to our attention the

Frye hearing that Dr. Brerard's most recent study is wrong in her calculations. They asked Nick on the stand to check her numbers, we dodged it, but after the hearing, here is what he -- so he went back and specifically found on the Zoloft numbers, Brerard is apparently wrong with her calculations, the correct calculations are, and they lay them out.

And frankly if you compare what those calculations are from Dr. Jewell, they're exactly the same as what Dr. Kimmel said. So PSC recognized there was something wrong, there's no significant findings and her abstract as well as the papers are incorrect. Someone should tell her before it goes to print.

So as of 2015, we know a few things. One is, we agree on this particular issue with the PSE that the study, the abstract is wrong, and we know that Dr. Jewell not only agrees, but actually crunched the numbers and looked at this either at or during the hearing, in order to come to the same conclusion.

So Dr. Jewell was deposed in May of 2015, and asked about these specific questions. He was asked whether independently assessed Dr. Brerard's data and his testimony is irreconcilable at best. He testified that he did not independently assess Dr. Brerard's data, that he was unable to check her data,

that he cannot tell whether her data was right or wrong, but of course, we know from the February 2015 e-mail that that is just simply not accurate. And perhaps it's because he didn't expect this e-mail would essentially be produced in this litigation.

So here we have another e-mail where there's another one of these open epi again who would've thought that you need more than one program to check epi data. But here, the PSE used another program, they checked the numbers for every end point, they were all correct except for the three positive numbers, the ORs, the odds ratios are the same, but her confidence intervals are wrong.

If there was something odd or unknowable about how she did the data, why would this program be correct for all the rest, except for the three positive significant association, does it make sense, but I don't think there's anything else we can do. Again, I probably couldn't have said that better myself, that's exactly the point, we agree.

Now, just to kind of -- if there was a need, a little bit of belt and suspenders on the final point of this, so we looked at it, PSE looked at it, Dr. Jewell did, Dr. Kimmel, everyone says it's wrong. So we went back, though, and looked at the actual

abstract. And the abstract is instructive, because it's using the same data set, the same information, right, this is before the actual published information.

And using the same information, you know what Dr. Brerard's abstract says? It says the same thing that we all say now with respect to the numbers being incorrect.

And as a result, this is, you know, for Your Honor's ready reference a portrayal of the information here. So we have the abstract numbers. We have what's been reported in this kind of orange slide of Brerard and then we have really what kind of both sides agree on is the data and the information that shows that it's not statistically significant consistent with her abstract. And again the outlier is Dr. Brerard.

Now, she -- in some of the e-mails she says, no, no, you're wrong, you don't understand it. But no one seems to understand it except Dr. Brerard. Now -- and Dr. Kimmel says unless we can figure this out, the findings must be deemed unreliable.

Now, let's turn to Dr. Jewell's methodological flaws, and there are a number of them, and Your Honor may recall we used a similar but not

identical slide to -- with Dr. Brerard, but that's largely because many of the same issues, notwithstanding plaintiff's view that his methodology changed, many of the same methodological flaws and issues applied equally with respect to Dr. Jewell.

His opinions are not generally accepted by the scientific community, we've seen that over and over again. He relies on inconsistent findings and false associations, relied on overlapping data. He improperly lumps heterogeneous cardiac defects, he relies on trends and non-statistically significant data, which Your Honor has addressed multiple times. Employs inconsistent standards, conducts post topry (ph) analysis, engages in situational science, and I'm just going to talk about some of the more salient issues because most of these are also covered in our brief.

So let's talk about Dr. Jewell's qualifications. He's not qualified to offer causation opinion here, he's just simply not, because the Third Circuit tells us, that qualifications are part of the reliability inquiry. And as I noted, we're not challenging the fact that Dr. Jewell is a statistician, and can crunch numbers and look at those types of issues. We're challenging his causation

opinions here, which he's not qualified, he's not an epidemiologist, he's not a medical doctor, he has no medical training whatsoever. He's not an expert in cardiovascular disease or cardiology. There's no dispute about any of this.

He didn't even consult, he didn't even ask an expert on cardiology when forming his opinions, hey, what is these different diseases, are the same, are the same from the pathogenesis. None of that happened here.

He doesn't have the expertise to say whether cardiac defects are anatomically, clinically or developmentally heterogeneous. Candidly says, hey, I'm not the person to do this for cardiac birth defects.

Despite those admissions and those lack of qualifications, he does seem to seek to opine that Zoloft essentially causes all manner of cardiac birth defects. And he's developed this catch all category of cardiovascular birth defects generally which as best as I can tell, means every single possible cardiac birth defect that one could imagine. He doesn't address even a single individual cardiac birth defect.

And what's really ironic, Your Honor,

for specific cardiac defects, things like heterodoxy (ph) or anomalist pulmonary vainest return. There are no findings individually. So there's nothing in the literature, yet his catch-all category would capture all of those issues.

The Court properly recognized that cardiac defects are heterogeneous and a specific exposure is not expected to increase the risks of cardiac defects generally. That's not the way things work. And while Dr. Jewell acknowledges that cardiac defects are almost surely epidemiologically heterogeneous, his report nonetheless opines only on cardiac defects overall.

This lumping is an unreliable methodology. Your Honor may recall this next slide, I won't read the whole thing from the last Daubert hearing, but this is from the (indiscernible) paper which is peer reviewed and teratology premer (ph), teratology organization, obviously like OTIS, an organization, doesn't -- it's sole purpose is to understand birth defects and help women and their families deal with them.

And in these papers, they basically call out and specifically say heart defects are heterogeneous. Putting aside all birth defects, they

specifically talk about them. For example, heart defects and heterogeneous and anatomy, development, epidemiological factors, combining different birth defects for analysis is valid only if the defects being lumped have an underlying pathogenesis that's similar.

And it's based on those principles in the real world when experts are looking at these issues that the Luac study authors developed seven categories, cardiac categories, and they lumped them or grouped them, excuse me, with respect to developmentally appropriate categories from a cardiac perspective.

This approach was adopted by the Peterson authors, they used these same sub-groups of cardiac defects that were created by the Luac authors. And as Dr. Shavastiva (ph) explained, lumping defects is unreliable and not generally accepted because they're a different heart malformations that are considered heterogeneous and involve different pathogenesis and physical manifestations.

So outside the courtroom, people don't look at these cardiac defects as a monolithic single event.

So let's talk about trends now. Dr.

Jewell is not shy about telling the Court that he is relying on non-statistically trends with respect to his analysis. And in their opposition brief, as Your Honor knows, the plaintiffs have attempted yet again to revisit the issue of statistical significance and argued that it's not required when assessing teratogenicity, but as Your Honor has recognized, epidemiologists who are examining potential teratogens generally will not draw a causal conclusions in the absence of replicated statistically significant epi findings.

And in excluding Dr. Brerard, the Court recognized that relying on trends in non-statistically significant data to draw conclusions about teratogenicity, rather than on replicated statistically significant findings is, in fact, a novel methodology. But it is a novel methodology that Dr. Jewell readily admits that he is relying on with respect to non-significant supporting trends and risks.

Now, even within that kind of trend analysis, and let me just say a word about this. The reason why Your Honor came to the conclusion and all of these other courts and the science is because what we don't want to have someone is to kind of give gut

reaction. Well, I've been doing this a long time, it kind of looks like a trend to me, it feels like a tetralogy, and I know enough about it, but you can't do that if you actually have statistical significance.

And that's how -- that's the yard stick by which Your Honor, other courts, and the scientific community largely measure and judge these issues. So this is an example of why this kind of trend loosey goosey analysis can cause such mischief.

This is an example, when you have non-statistically significant data, okay. So Dr. Jewell looks at it and says, non-statistical significant, (indiscernible) ratio, is it a protected effect, and to be clear, I think Your Honor knows is we're not suggesting that Zoloft or SSRIs, even though you can find blips, we're not suggesting they're protective, we're just suggesting there's no association between cardiac birth defects.

What he says is, if you look at this odds ratio that is in the protective effect, it's compatible with an increased risk. This one on this side of the line is compatible to increased risk. Why? Because well if you look at the upper bounds, this 1.23 if you look at this, it crosses one, so let's kind of ignore this, but this is trending in the

right direction.

But then when we have an odds ratio that's just kind of a hair over one, he says, well, that also, it's non-significant, but that's supporting a trend and risk.

So what you have here really is kind of a heads I win, tails you lose approach. As I understand Dr. Jewell's analysis, the only time you actually find something that unequivocally doesn't increase risk, or doesn't cause birth defects is if we had something like prenatal vitamins where we had multiple studies on the left-hand side that were all statistically significant.

And, of course, this is not how science is supposed to work, Your Honor. This is actually -- this data is from the Callen (ph) study. I think we've heard it's pronounced Chaleen (ph), for our purposes, we'll call it Callen or Kalen. And this is from the Callen authors. Did the study authors say, hey, our data shows that it's compatible with an increased risk. Did they say, hey, our statistically -- not statistically significant data supports trends in increased risks, of course not.

What they concluded was that the use of SSRIs is not associated with any increased risks of

birth defects with Paxil being a possible exception. Again directly contrary to the way Dr. Jewell reads this data and significant other data, and it's just simply not reliable.

Dr. Jewell also tortures the data, and that's admittedly a strong word, but I think we chose our words carefully in that regard, Your Honor.

Now, Professor Ron Corce (ph) is I think credited with this statement, if you torture the data long enough, it will confess to anything.

Now -- and the reason why is that the statisticians and others recognize that doing so leads to spurious results and a serious distortion of the significance both statistical and clinical of the findings.

This is a graphic from the manual on scientific evidence. It's, I think, basic but instructive, right. The idea of a cohort study tells us you look at the population, you try and find people who were exposed, you try and find people who were not exposed, and then you look at the exposed group, hey, did it cause any adverse issue or disease.

Not exposed group, any adverse issue or disease to find out background and that's again, somewhat basic, but I think instructive view from the

manual about how things are supposed to work.

And this is a concept that Jiminea and Solom authors really were -- it's quite brilliant in what they thought about. So let me see if I can explain again. I know Your Honor is generally familiar with these issues, but it's been a while, and we also know this is not Your Honor's only litigation.

What Jiminea and Solom tried to do, is they recognized, everybody recognized that this concept of confounding is important, right. Is it something about women who are depressed, who are having these other issues that's causing them perhaps to have negative birth outcomes, or is there something about SSRIs, or the medicine, right, so that's what they wanted to find out.

So they said, you know what, let's take a group of women who were depressed because they were on -- and they looked at medical records, they were on SSRIs, right. We're going to look at the medical records and we're going to find those women who actually stopped taking an SSRI more than three months prior to conception based on the medical records, whether they did it intentionally or no one knows, or how they did.

But they were able to say, this is a

paused group, they're not exposed. These women also went back on SSRIs after they gave birth to their children, right. But we know they were not on an SSRI during, at least for the purposes of this hearing, a cardiac development phase of 2 AABs (ph). So that's one group.

And then they looked at women who basically were depressed, were prescribed an SSRI and never paused, just continued taking the medicine all throughout their pregnancy and their conception.

So what did Jiminea and Solom find? What Jiminea and Solom found, even had some ironic results, look at ventricular septal defect. This is women who were paused who never took the medicine. They actually had a higher risk. Now, this is elevated as with respect to the background of women who were not depressed and never took it, but it's highly people -- women who were taking the medicine all throughout their time, their pregnancy.

And even these other numbers, they're basically all the same, right. So what is the conclusion here? The conclusion is, hey, is there something about these women, is it the medicine, well, no, because we're seeing the same thing about women who were depressed and already taking the medicine.

So they concluded in their peer review publication the risks related to SSRI use during the first trimester are a result of an unaccounted confounder (ph), it's not the medicine.

What does Dr. Jewell do with this? He says, I read Jiminea and Solom as saying, Zoloft exposure was associated with a nearly tripling of the risk of cardiovascular defects. Go back to that slide. I mean, is that what these authors say is the result?

In fact, next slide, please, looking at their own data, did they say, my gosh, I found a threefold, 300 percent increased risk between Zoloft and birth defects. I don't think so. What they said is we believe that the present study brings us one step closer to a verdict of not guilty for the SSRIs based on our findings, reports, have recently emerged suggesting that SSRIs should be acquitted from being major teratogenic agents. That's looking at their own information and their own data.

Now, another example of this torturing of the data comes with respect to the Hibrex study. And Hibrex, as we discussed is the largest, most powerful study to date, and it found no statistically significant association of cardiac defects with

Zoloft.

Here, Dr. Jewell tortures that data to reach a conclusion that's not only inconsistent, but frankly contrary to the Hibrex authors' approach and conclusions. And it suffers from serious methodological flaws.

Now, Hibrex compared as the manual tells us they should, exposed versus non-exposed. I think what sometimes gets a little muddled here and a little confusing is what Dr. Jewell tried to do is use this data, which the Hibrex authors never did, to create something called the pause group. Remember, the paused concept was Jiminea and Solom, these folks never talked about pause. They had their own kind of peer reviewed approach, and their approach was to basically use this three-step analysis, and at each step, you were to adjust for confounding, for these other factors, did they smoke, were they obese, did they have a family history, a host of other factors that were all pre-listed.

And -- next slide, please. To show how Dr. Jewell tortures this information, because he didn't have this exposed versus non-exposed in the Hibrex data, he said, well, me try and create my own paused group. But admittedly, this is his slide, and

this is his footnote, he said, I'm going to use -- call people pause, and remember Jiminea and Solom pause meant you weren't taking the medicine. I'm going to call Jiminez -- I'm sorry, Hibrex group paused even though they were classified by the Hibrex authors as women who were using the medicine. So that means you're comparing exposed to exposed, which makes no sense, and is not methodologically appropriate.

And we know that there is -- next slide, please, only one reason why Dr. Jewell tried to contort this information in a way that makes no sense from a methodological or scientific perspective.

Now, in some of the documents that were recently produced by the plaintiffs, it reveals Dr. Kimmel is not alone in his methodological criticisms of Dr. Jewell's post-hoc analysis of Hibrex.

So we know Dr. Hibrex, the lead author of the study after her name, shares the same concerns that Dr. Kimmel has. And we know this because Dr. Jewell e-mailed Dr. Hibrex and asked her not just a question about hey, what does this mean or what's the study, basically e-mailed her on July 6th, and said, I was wondering whether you might be interested in joining me as a co-author on a publication about these issues as I think other investigators might find these

and related results to be of interest.

Now, Dr. Hibrex gets this, and she sends several e-mails back, specifically on this point. And this is what she says. She's basically saying a number of things, and you'll see them from her words, but my words are, why would someone do this, it doesn't make sense, why wouldn't you rely on the peer reviewed data, and you can't control for confounding which is essentially the main point of why we did this entire study. I don't think I follow how you conduct an analysis, based on the concept of pausing, just what Dr. Kimmel has said. It appears you compared patients that filled a prescription during the first trimester to patients who had days' supply overlap but did not fill a prescription.

So again, she says, as we're saying, is that Dr. Jewell improperly compares an exposed group with an exposed group.

And again, this is what Dr. Kimmel said. The paused group is in fact not paused, the comparison that Dr. Jewell makes is really among women who are exposed to Zoloft during the first trimester, the exposed group had a prescription filled during the first trimester, or one that lasted into the first trimester.

And again just -- without getting too much into the weeds, Your Honor, really what Dr. Jewell said was, I'm only going to look if somebody -- I'm going to recharacterize it, because I didn't see they filled a prescription in the first semester, I'm going to say they weren't exposed.

Well, as Dr. Hibrex and Dr. Kimmel and (indiscernible) said you don't have to be a scientist said, well, what if happens if someone filled a three month prescription a day before or a week before they were conceived, knowing that cardiac development is within the first two, or three, or four or five or six weeks.

So, of course, it's completely artificial to try and create this scenario just for litigation purposes.

I don't see how you can account for potential confounding this way, doing such analysis would be useful if there was a concern about confounding by depression and its associated factors, given that the overall analysis are peer reviewed million person data, showed a no association and residual confounding is not a concern, what would be the value of such an analysis. Why would you do this?

And what's particularly interesting is

this is a person who's never published before, he's never published on these issues, or saw a fit in his regular life and duties to publish, but now he's interested apparently in publishing certain data that Dr. Hibrex finds is completely unnecessary and contrary to her report.

And he says, I'm not able to make adjustments for confounding, as I would need raw individual data for at least the two sub-calculations to be able to do this. And that's right.

And finally what she says is, hey, politely, but she says, it would be surprising for a post-hoc analysis subgroup, post-hoc subgroup analysis like the one you're proposing to supersede all other pre-specified information that we've been working for years on.

And again, this is consistent with what Dr. Kimmel has said before he knew Dr. Hibrex knew from these e-mails the plaintiff subpoenaed, the most reliable and thorough analysis of Hibrex come from their own published studies, which clearly document the importance of confounding.

Now, I think and I don't want to be quoted on this, but I think at one point, maybe it was one of the prior hearings, Dr. Jewell said, his

analysis, his Hibrex analysis is an exquisite analysis. Okay.

Well, if it was really an exquisite analysis, wouldn't you have expected him to employ that with respect to his work in connection with Prozac. Does he? Well, I think Your Honor probably knows the answer to that. He doesn't for one reason. Because if he used the same analysis that he's trying to use before Your Honor, to show that this new two-step process versus the three-step process from Hibrex, he likes these numbers, because they support his analysis. Didn't do that analysis in Prozac, because they would be absolutely contrary, and that's one example of situational science as well, which leads us to our next point.

Courts certainly disfavor situational science and experts' opinion in another case that may reveal whether the expert is genuine and is properly following some scientific methods with integrity or -- I'm sorry.

An expert's opinion in another case may reveal whether the expert is genuine and properly following some scientific method with integrity, or simply in the business of expressing whatever opinion is helpful to the party hiring the expert.

And I think for this purpose, we can compare what Dr. Jewell did in Prozac and what he did in this litigation. It's not a scientific methodology. It's advocacy.

We start with really an interesting kind of jumping off point, because this is from his reports. If you literally, and you can take my word for this, when Your Honor -- kind of changed Prozac, right, and the chemical name, it's the same thing, so I was asked to do the same thing. I was asked to look at here's my method. For this report, I was asked to limit my inquiry to cardiovascular outcomes. Again, it's all the same.

So again, if you were asked around the same period of time, looking at SSRI, given the same job, if you weren't engaging in situational science, you would think that you would follow a standard methodology. Well, let's see if Dr. Jewell did that.

So here for reasons apparently only known to Dr. Jewell, he said, I focused my review on peer reviewed studies that provided original data for cardiovascular birth defects related to maternal exposure to Zoloft during pregnancy. Okay. That's what he said he's going to look at.

Interestingly for the same method, with

Prozac, I focused my review on numerous meta-analysis that reviewed and analyzed data related to maternal exposure. You can see, Your Honor, the differences there. Meta-analysis bad Zoloft, meta-analysis seem to be good Prozac.

Let's talk about the Miles (ph), which is -- the reason why Miles is so important, he referenced it earlier, Your Honor, but Miles is a peer reviewed recent meta-analysis, okay. With respect to Zoloft, next slide, please, this is what the authors had to say, and then you'll have to draw your own conclusions as to why Dr. Jewell determined to exclude meta-analyses.

Zoloft should be considered as a first line SSRI treatment in pregnancy in women of child bearing age, Zoloft was not significantly associated with congenital malformations.

What did they say about Prozac though? Prozac should be avoided in the first trimester, and among those at risk to an unplanned pregnancy, some consideration ought to be given to whether Prozac should be placed with Paxil as category D medication; very, very different findings with respect to those issues.

In our litigation before Your Honor, he

rejects Miles. It appears the investigators might not have followed their own predetermined inclusion/exclusion criteria. He's pretty harsh with them, given the methodological flaws, I do not find Miles scientifically reliable when considering the specific effects of Zoloft exposure.

Does he find the same flaws when he's writing a Prozac report? It appears that there was inconsistent application of the data, similar, but here, those flaws become issues. And even with those methodological issues, Dr. Jewell repeatedly quotes from Miles and relies on it, and specifically likes the part about consideration might be -- ought to be given to whether Prozac should be placed with Paxil as a category D.

You see, Your Honor, where the plaintiffs fought so hard to keep us from getting this -- these reports.

There's another example, which is the McDonagh (ph) meta-analysis. And, you know, I think Your Honor is perfectly within the realm of determining why someone would choose to only look at studies but not meta-analysis in one litigation versus another.

So let's look at McDonagh. McDonagh,

no increased risk for major malformations, no increased risk for cardiac malformations, but with statistical heterogeneity upon the sensitivity analysis, reduced risk of cardiac anomalies inconsistent with Dr. Jewell's approach.

Whereas with Prozac, it's statistically significantly associated with an increased risk of major malformations. Prozac is associated with an increased risk of cardiac malformations. Zoloft good, Prozac not so good.

Extremely dismissive, both in his deposition and throughout. I don't think it's worthy of discussion. In fact, until he was asked about this study, Your Honor, at his deposition, he said, why would I even bother with that, I don't think it's worthy of discussion in my report.

He then later went back and had to comment on it, but he didn't find it worthy of much comment in my original report, ultimately I cannot rely on this meta-analysis in our litigation.

Is that true for Prozac? Again, of course not. He embraces McDonagh, he talks about how, you know, attempting to prompt this up, this was prepared for this U.S. Department of Health and Human Services Agency, it was issued recently in 2014, it's

a well done study, and he relies on it significantly.

The authors conclude that the best evidence of the risk of cardiac malformations, you know, again a statistically significant finding and the authors concluded that Prozac is associated with an increased risk of cardiac malformations.

Rarely, Your Honor, do you have this stark of an example of situational science, which is really no science at all.

Now, I want to move to my last category, Your Honor, and this is the misrepresentation of company documents. Of course, Your Honor will probably -- most Courts would write something similar that reliance and phrases plucked from corporate documents don't prove or provide scientific evidence of causation under Daubert.

And what is also kind of -- to me at least somewhat ironic, while Dr. Jewell talks about some of these, and we've seen them in prior openings, and when the jury had a full chance of seeing them, we know what their conclusions were. But on the one hand, he includes them in his report, but on the other he says, hey, none of my opinions are based on this, I don't rely on them, you know, they're essentially didn't help me form my opinions.

But let's talk briefly about these two categories that are frankly misrepresented. The first is a PSUR. It's a one page out of a 50 plus paged document, and of course, the PSUR which is a Periodic Safety Update Report has to do with something called growth retardation in children and adolescents, not birth defects. It was not designed for and didn't present a complete review of the literature on Zoloft, and everyone agrees with that, when you see what they talked about, it's not complete.

This is actually the front page of the PSUR, and it's dealing with growth retardation in children and adolescents. The plaintiffs rely on this one page over and over again in their materials.

But let's talk about, you know, we know that obviously this was not focused on birth defects. There is a section on it. We also know that the search terms they used wouldn't capture the state of the art data, and in fact, they didn't capture the state of the art data because -- next slide, please, it only cites three studies, it's not a complete review.

And what I think is really important, based on what we know really in the last, you know, month or two, one of the findings that we're relying

and here's Luac, which at the time, everyone in good faith believed was statistically significant, but now we know it's not.

So if and when Your Honor sees or appreciates this, I think some of that background is important. And, of course, this is, you know, kind of a breakdown that by admission that PSUR doesn't address all of those studies on the top, and when it says that there was consistent findings, in fact, we know and Dr. Jewell agrees that there's many studies that have negative associations.

Now, there's one other kind of document that or maybe two documents that we believe are and have been misrepresented and really taken out of context. I think the Court -- just give Your Honor a brief capsule here, a time capsule of what happened.

So the issue here is that an April 2014 document or PowerPoint that was based on a document from a Pfizer employee, and it talked about four studies. So let's talk about that.

So March 2014, the FDA said to Pfizer, hey, we're -- informed Pfizer that it was in the process of updating Zoloft label, and as is customary, the FDA asked Pfizer to review the published literature on whether Zoloft is associated with

teratogenic defects when used in pregnancy, and provide language to update the section. We're looking at your label, give us some information to update it.

This was assigned to a woman employee at Pfizer, named Ms. Kolitsopoulos (ph). And she wasn't on the Zoloft team, as I understand it, but she was assigned this task, and she did an initial review, a two week review of this information. And she sends an e-mail of kind of what she had found at that point, what she believed her charge was.

And we know that it was obviously incomplete and a work in progress because she only relies on five studies. We've probably talked about, you know, two dozen or so, and one of them doesn't even include birth defects. So she didn't capture kind of the universe we know, of course, at that time.

She then prepares a PowerPoint essentially two days later, or maybe it was a work in progress of the same information, and she says that evidence from the epi data studies assessing the risks of Zoloft exposure during pregnancy have demonstrated inconsistent results, it lists the five studies. As I said which is clearly incomplete, and it includes one that's a birth defect, not a birth defect study.

And then when she says, and plaintiffs

have kind of seized on this, or attempted to seize on this, is that, although the data not conclusive, there's suggest of an effect, but of course, when you ask a scientist, an expert what suggests means, it's a proposition, it's a hypothesis that requires further research. And we know that not only from the science, but we know that because that's exactly what happened.

And again the reason why, just putting this in context, Your Honor, is because there's been some kind of either implication or outright statement that hey, you know, what Pfizer is saying in its internal documents is somehow disparate or completely different than what, you know, they're telling Judge Rufe in this courtroom or somewhere else, where they actually believe that it causes birth defects.

But this should put that issue to rest. Initial were questions, nothing goes to the FDA. Then in April, over the summer, months and months, Ms. Kolitsopoulos with a team of other folks look at this issue as you would expect them to do with something as important as this.

And then in September, she says I'm almost complete with my review, and would like to discuss my findings and next steps Thursday or Friday. She then with the benefit of all the work that she's

done with the team, she e-mails the results of the literature which now includes 13 studies.

And this is what she says, potential methodological issues noted by the study authors that could have impacted the results of these studies include uncontrolled confounding by indication, medication not compliance, incomplete report, medication recall bias, multiple testing, small number of outcomes, detection bias in which women -- in which children of depressed women on pharmacological treatment are more thoroughly examined for malformations than other children.

She's now kind of gotten her hands dirty in a little science, and many of these issues, frankly, are things that both sides agree with. And then what she says is, given the scorings and study findings and methodological limitations of these studies, the data and Zoloft use and risk of congenital birth defects are inconclusive, that's her conclusion after she looks at the data, and has a fit full and fair opportunity. And not only is it her conclusions, the team's conclusions, but based on that information, not a two week analysis in April, Pfizer takes it, reviews it, and they send the information to the FDA in October.

Do they say that Zoloft causes birth defects? Of course not. At this time, given the discordance and study findings and limitations and methodology, these studies discussed in this response, the data on Zoloft use of congenital birth defects are inconclusive, given no compelling evidence for risk of congenital birth defects associated with the use of Zoloft, continuation of the current labeling is recommended.

Now that, Your Honor, is what Pfizer is saying in January of 2015, is what we've been saying since the very first time I had the pleasure of appearing before Your Honor in this MDL.

And then in January 2015, Pfizer sends a letter to the FDA, based on this information saying, hey, we've now done what you've asked us to do, based on the results of this comprehensive review, it's concluded that there's insufficient evidence to suggest that there is a causal relationship between Zoloft use during pregnancy and congenital anomalies.

Data from these studies of pregnant women in the first trimester to determine the risk of major malformations are inconclusive. Overall, a causal relationship has not been established. That's Pfizer's position then and now.

So -- and then finally, you know, perhaps we -- in this regard at least, the benefit of moving this hearing, there was something very interesting that happened just a few weeks ago, Your Honor.

The FDA actually just came back, remember that whole timeline, the election of information, writing all the studies, writing the information, they came back and said, this is what we think your label should be, August 2015. The weight of evidence from epidemiologic studies of pregnant women exposed to Zoloft in the first trimester suggests no difference in major birth defect risk compared to the background rate of major birth defects in pregnant women who were not exposed to Zoloft.

Again, proposed labeling, a meta-analysis of studies suggest no increase of the risk for cardiac malformations among offspring of women for the first trimester exposure to Zoloft.

Ironically, the FDA as opposed to Dr. Jewell relies on Miles. And this is, I believe, my second to last slide, Your Honor, but this is what the FDA proposed based on all of the information. An increased risk of congenital cardiac defects specifically septal, the most common type of

congenital heart defect was observed in some published epidemiological studies for the first trimester exposure.

However, these studies were limited by the use of comparison populations that did not allow for the control of confounders, such as the underlying depression, which may be independently associated with these malformations.

So that's where we are, Your Honor. That's the complete story as to those documents, and I guess I would just conclude basically I think where I started, you know, Your Honor, there are just so many methodological flaws that are part and parcel of Dr. Jewell's opinions, that you have to ask kind of why is it, why would someone have to jump through all those hoops. And the reason is really clear.

The reason is, this story should write itself. The data, the information that's out there, that's available to the FDA, all of these organizations tells the story that there is no causation.

If you're going to want to change that story for litigation purposes, you have to engage in all of these things, you have to do post-doc analysis, you have to apply different standards. You have to

kind of ignore certain scientific principles. You have to rely on overlapping data, and non-statistically significant information. And when you're dealing with something as important as the issues are in this case, and Your Honor has spent -- and your staff, you know, a kind of overwhelming amount of time, it's really important to make sure that what the expert is hoping and trying to do in this courtroom is consistent with what he or she is doing outside this courtroom, and I think Dr. Jewell clearly fails that test. Thank you, Your Honor.

THE COURT: Thank you, Mr. Cheffo.

Who will be addressing the opening for the plaintiffs?

MR. ZONIES: Good morning, Your Honor, Joe Zonies.

THE COURT: How long do you think you'll be, Mr. Zonies?

MR. ZONIES: It's going to be, according to my slides, probably about an hour, an hour and ten minutes.

THE COURT: Okay.

MR. ZONIES: Yeah.

THE COURT: Okay. Then we're going to take a brief recess before you start.

MR. ZONIES: Well, yeah, and that's actually I think wrong.

THE COURT: Oh, don't go by that. Never go by that.

MR. ZONIES: Okay.

THE COURT: I think it's almost 12 o'clock.

MR. ZONIES: Right. Mr. Cheffo discussed that before (indiscernible) or you want to do lunch now and then come back (indiscernible) confer with counsel and maybe I'll stipulate, and we can just go straight to testimony.

THE COURT: Well, what's -- I have no problem with having an early lunchbreak, but not a long one.

MR. ZONIES: Right.

THE COURT: So 45 minutes is a good suggestion and do what you have to do with your colleagues. I see some of them have arrived.

MR. ZONIES: Yes.

THE COURT: The planes, the traffic is just miserable today. It is a holiday week. So we will come back in 45 minutes, which will be 12:45.

MR. ZONIES: Thank you, Your Honor.

(Recessed at 11:55 a.m.; reconvened at 12:50

p.m.)

THE CLERK: All rise.

(Call to Court)

THE COURT: Good afternoon. Please be seated.

MR. ZONIES: May I approach, Your Honor?

THE COURT: Yes, please do.

MR. ZONIES: Your Honor, I have a copy of a notebook for the Court.

THE COURT: Thank you.

MR. ZONIES: Documents that are simply objected evidence, it's Dr. Jewell's report which I'm sure will actually be called subjective at least to some, but in the primary studies cited.

THE COURT: So you met with your colleagues and you are going to open.

MR. ZONIES: I guess they just can't wait to hear from me.

THE COURT: Well then proceed.

MR. ZONIES: Thank you.

I had a fairly straight forward Daubert presentation and opening ready, but I had to switch it up a little bit because of a few points that I want to make. Because in the context in which it was

presented, I would agree they seem quite strong issues.

One is the difference between whether or not to use meta-analyses and whether or not Dr. Jewell had situational science. And what I would say and posit for the Court is, that Dr. Jewell actually had good science, in depth science, the typical science that the Court will see throughout his report and I really encourage the Court to reread that again.

Because what Dr. Jewell did in Prozac as compared to Zoloft is scientifically correct. And the thing that made me switch this up a little bit was, Pfizer knows that. They've asked these very questions before. Pfizer knows the reasons that Dr. Jewell has done this. And Pfizer not only didn't address those reasons, Pfizer obfuscates and hides the reasons.

Here's a quote that was put up on slide 82, and you'll see across the top, that's actually -- those are accurate quotes. It appears in Zoloft they may not have filed their own predefining (indiscernible) exclusion criteria, it appears inconsistent application inclusion exclusion criteria in the study, that both reports recognize that potential flaw with the Miles analysis.

Oddly the analysis that Pfizer has convinced the FDA (indiscernible) as far as we know. But then here's the quote that got me a little bit upset. Given the methodological flaws in Miles . . . I do not find Miles scientifically reliable.

That looks like it makes sense. In Zoloft, he says there's a methodological flaw, and then he says, I don't find it reliable. And in Prozac he says, oh, there's a methodological flaw, and even with it, I'm going to include it. I too, would be upset, but Pfizer knows that's not actually what happened.

Because the . . . is actually a little bit important. I've handed to the Court a binder with Dr. Jewell's report as Exhibit 1. What he actually says about Miles in his Zoloft report is, unfortunately given the methodological flaws in Miles, the inclusion of studies that should have been excluded per protocol, and their apparent lack of understanding of heterogeneity, I do not find Miles scientifically reliable when considering the specific effects of Zoloft exposure.

The . . . actually included a lot of stuff in it. One of the things that the . . . included is statistics. And what statistics means in

this context. Heterogeneity. Could you please switch to my PowerPoint.

UNIDENTIFIED: Joe, do we have a copy of that one?

MR. ZONIES: I don't think I have a copy, we'll print them out.

Prozac expert report now Lilly's (ph) counsel from Ms. Gusset's (ph) office is here, they knew this, and Pfizer fought hard to get this report, and we didn't actually push back. I think Mr. Boise (ph) might admit he had something to do with it. Why wouldn't we push back? Because Dr. Jewell is very clear in his use of meta-analyses between Prozac and Zoloft.

He says, such an issue is addressed by examining the heterogeneity effects across the studies using standard statistical methods. For example, in Miles discussed below, there were statistically significant heterogeneity when assessing the risk for Zoloft in malformations. This calls into question the summary provided in Miles for that drug; however, on the other hand, when examining Prozac, the heterogeneity was moderate and not significant.

There is a scientific basis for a differential treatment of Miles in the Prozac context

and in the Zoloft context. We agree with Pfizer in this context that it's not class effect, it shouldn't be applied similarly across these drugs, that's what Dr. Jewell had said. One of the Court's early concerns with Dr. Brerard, Dr. Jewell has intentionally not done that. Had he done that, he would have used this and quoted the Prozac results in this case. He can't, because statistically it's not permitted.

What is heterogeneity? Heterogeneity is you have all these different results, and if someone asks you, hey, tell me what wine tastes like, and you mix all those together, you're not really going to get a good idea of what wine tastes like.

It's a recognized issue in all of science, including the reference manual on scientific evidence for the federal courts. The key issue is a matter of heterogeneity results among studies being summarized, but there's more variance than one would suspect by chance. There is further uncertainty about the summary measure from the meta-analysis. Dr. Jewell applied good science, not what is called situational science.

Now, Dr. Kimmel is not a statistician, but one can presume hopefully that Dr. Kimmel like

Miles would know about the heterogeneity issue. Certainly Pfizer was aware of the heterogeneity issue, because they had this report at their insistence.

They have also heard and cross-examined Dr. Jewell on this very issue a number of times, and Dr. Jewell has explained it to them. And unfortunately for the Court what was presented was instead a slide making it look like Dr. Jewell decided to do two different analyses. You can even back it up a step further, when they say, huh, Dr. Jewell here says, I examined the individual studies and the data, and in Prozac Dr. Jewell decided to use meta-analyses.

Well, again, Pfizer knows what that happened, they've read his report, they've also cross-examined him on that issue a number of times. Why would that be? Well, unlike Pfizer, Ely Lilly, the makers of Prozac determined to do a meta-analysis of their own on their drug of 18 studies, and that meta-analysis led to a label change for them about cardiac events.

Pfizer has yet to date to ever do a meta-analysis. Their experts won't do one, if they want one so desperately. Why? It's not proper.

You cannot do a proper meta-analysis on these studies, on Zoloft studies. Why?

Heterogeneity.

Here is from Miles in the Miles chart pulled right out, and you can see the difference between Fluoxetine, Prozac, where heterogeneity which is measured here by its P value for significance, and also it's I square value which is the magnitude of the heterogeneity, and you can see that virtually there is indeed significant open magnitude and statistically of heterogeneity. That means that it is not proper to do the meta-analysis, or you can do it, but the results are not necessarily reliable.

So again, in the slides when they present this Prozac issue on slide 82, even with these methodological issues, quote -- it's a quote and then the quote ends, Dr. Jewell repeatedly quotes Miles.

Dr. Jewell's full sentence in Prozac says, even with these methodological issues, meaning the inclusion/exclusion criteria, the fact that there was not heterogeneity or it's not significant heterogeneity or a great magnitude, and because my primary piece of evidence is Lilly's meta-analysis and these results are not inconsistent with that. Miles is a supported study.

So in the absence of that context, a context well-known to Pfizer, it's really not fair to

Dr. Jewell in particular and to this Court to present this slide making it look like Dr. Jewell is using different methods in two different litigations because he wants the outcomes to be right. That's not fair, and it's not true, and they know it.

The same with McDonagh. There are three meta-analysis that I'll talk about today. Miles, McDonagh, otherwise known as an AHRQ, and the Wang (ph) recent meta-analysis. And Dr. Jewell will go into some detail about each of those, but this is McDonagh's meta-analysis, and indeed as Pfizer puts in its brief, Dr. Jewell does say the best evidence in the Prozac litigation, the best evidence of -- because he's quoting from the chart, which is called best evidence, he's not making a determination of that -- the best evidence for Fluoxetine is on here -- is a 1.3 statistically significant increased risk, what's the hetrodyne, the (i) squared, zero percent. Sertraline, what's the hetrodyne, 68 percent.

Dr. Jewell is very clear about these issues in his two reports. He's testified about them numerous times, and Pfizer knows it.

Another issue that came up was the Luix and Allen Mitchell emails back and forth, and the regression analysis that was provided, and

unfortunately for some reason -- well actually they received it late last night, I'll assume that's the reason why this didn't show up in the presentation for Pfizer -- but when the authors were asked about why the regression analysis appeared to have additional confounding factors from the published papers by me, this is the response we received yesterday afternoon, and it's essentially saying that, oh, looks like we messed up again, and we'll be going back to the Journal to fix it again.

So while Dr. Mitchell says we regret this error about which we are communicating with the Journal, but wish to clearly state that the risk estimates in the regression, which we provided, are correct. Well they're correct for that analysis, but it appears they may not be correct for what was actually published. And again, there's more detail on that later, but these new Luix figures continue to evolve.

With regard to Dr. Berard it's a strange subject in this courtroom for both sides I think and for the Court. What the Court said about Dr. Berard was about her methodology that she used in this courtroom as an expert witness. And in fact during Dr. Berard's testimony and at other times, the

Court made it very clear that you weren't and wouldn't question Dr. Berard's methods in her own studies. In fact one of your concerns was is that Dr. Berard seemed to applying different methods in court than she did in her own published papers.

Dr. Berard's 2015 paper is a published, peer reviewed paper, that no one has questioned. Pfizer hasn't written a letter, Dr. Kimel, as far as we know, hasn't written a letter to the editor saying, what is going on here, this is crazy. And again, this is something that Pfizer either knows or should know about Dr. Berard's study, which is the results -- because in part they have the emails -- the results are complex because of a statistical method about which Dr. Jewell has actually published, that was used in the paper. And it's not a statistical method that was made up after the fact to get things to look significant in some way.

If she were doing that one would think she would have done us a kick and done it for all cardiac or something like that. But she didn't, she reported her actual results. Crude and adjusted, both, were calculated using generalized estimating equations models. That's a nuance term in statistics that apparently Dr. Kimel either ignores or doesn't

understand, but in this courtroom by this time they should understand that because Dr. Jewell testified about this in his deposition extensively, and Dr. Jewell testified that this method makes it impossible to do what Dr. Kimel did. How do we know it? Dr. Berard, yes, did I -- did Ms. Shaver (ph), I, send Dr. Berard a question saying, why can't I get these confidence intervals that you're getting? Yes, because Pfizer questioned them, we can type them into MedCalc like any other person can or Open Epi and find out, well, this -- something is weird here. And her response is, is there's no way to calculate the confidence interval with the numbers in the paper. It is a match multivariate model. The numbers are right.

What does that mean? These are adjusted for repeated measures, women with more than one pregnancy within the time period, all variables that are at the bottom of the table. We use GEE models, my biostatistician redid all the models yesterday, so we put her through some extra work because of (indiscernible) because we have women who have multiple newborns with atrial septal defects or crainiosynostosis, the variance calculated for the crude using the frequencies in the table, in other words, the table that Ms. Shaver had supplied, is

incorrect. You need the raw data to calculate the estimates. You need the raw data in this model because of a standard statistical methodology that is explained very clearly in the methods of the paper. It should be clear to any biostatistician or epidemiologist upon that review that these numbers are solid and running them in a MedCalc isn't going to do it.

Now, does Pfizer know that? Yes. Dr. Jewell's deposition was taken. Did you independently access her data? I looked at her -- to finish the sentence -- I looked at her confidence intervals and was worried that they didn't match. So, no, I did not access her data, the underlying data. I looked at her data that was in summary form on the two tables in the paper. And actually the first time that I was asked to look at that data was by Pfizer's counsel at Fry (ph), which she requested I analyze the data for an earlier version.

Table two presents enough basic data to double check the risk ratios, which is what he did on the stand at Fry. He said, I can tell you that her risk ratio was correct, but you can't do the confidence intervals.

Now in this question Pfizer's counsel

either doesn't know that, but after this question does. Wait a minute, the basic data is there and the confident, you can do crude data confidence intervals. No, that's not correct. Why is that incorrect? Because you need the raw data to check. Not to check the risk ratios perhaps, though even that is a little unsure. You don't have enough information to get the confidence intervals from the paper.

Now, Dr. Jewell knows that because this is a statistical method that Dr. Jewell is familiar with and has applied and is in every textbook on epidemiology, and it is an advanced technique used in pregnancy because what it does, is it accounts for multiple pregnancies with the same woman and tries to analyze, is there a difference there that makes an impact, much like the sibling analysis in Furu (ph) and much like the sibling analysis in Wemocker (ph), although I'm simplifying it, Dr. Jewell would have to some more justice to that.

Dr. Jewell clearly informed Pfizer at this deposition months ago, assuming the OpenEpi results are the right -- assuming the OpenEpi results are the right thing to do for this data, that is what's incorrect, and that's what Dr. Kimel failed to recognize. Why do you say the OpenEpi is incorrect?

Because neither you nor Dr. Kimel read the statistical section apparently in Dr. Berard's report where she specifically highlights that that's not what she or her statistician did.

Pfizer knows this before they come into this courtroom, and Pfizer refuses to let the Court know as it presents this information that Dr. Jewell has a very sound scientific reason for relying upon Dr. Berard's published peer review data.

Dr. Kimel did a two by two analysis. He computed crude odds using OpenEpi, and I assume he just plugged them in, which is also what I did not knowing that Dr. Berard had applied the GEE. So Dr. Kimel and I suffer from a similar misunderstanding of the nuances of statistics.

So those were just three issues that I wanted to bring to the Court's attention today that I hadn't anticipated moving to the front of my presentation, because I had assumed that Pfizer would have informed the Court, or frankly, wasn't going to go into each of these things, because Dr. Jewell's testimony on this in multiple other contexts has been very clear that what he has done is not situational science, it is good science. It just requires an understanding of the science.

So, I'll back up now to where I would have started, which is this is today a Daubert hearing. It's not about conclusions, it's about methodologies that were used in reaching a conclusion about whether or not there's a causal association between the use of Zoloft in the first trimester and cardiac heart defects.

Dr. Jewell's qualifications are well-known to the Court, including his book entitled Statistics for Epidemiology.

This methodology is the same methodology that Dr. Jewell has applied in his entire career, as far as I'm aware, the same that he applied in this court previously. Dr. Jewell gathers the relevant literature, extracts the relevant data, he examines the associations in that data, and he accesses, as only a scientist can, whether the associations are a function of one of three things, because that's all an increased risk can be. It's either due to rain of chance or it's due to bias, which includes confounding, or if not, the associations get accessed for causality under Bradford Hill.

It's not a different methodology than anyone else has applied. Dr. Kimel has previously

testified that that is a valid methodology, and in fact the same one that he used, and Dr. Shurvastava (ph) has said the same thing.

The concern that Pfizer seems to have is with the way that these were applied, not with the methodology itself, and primarily with the conclusions that Dr. Jewell reaches.

So, gathering the relevant literature and extracting the relevant data. There is science involved in this, nuance involved in this. You have to define what it is you're looking for. And for Dr. Jewell he predefined what he was looking for a peer reviewed, published papers with original data, with Zoloft specific results for cardiovascular birth defect outcomes. Those were his four criteria, and this is in his report, and he found 11 what he calls core studies, and those are listed there.

Peer reviewed original data reported as an odds ratio for Zoloft in particular in cardiac birth defects. In doing so Dr. Jewell was mindful of, although this is I think how he would have done it even before the Court's concerns about class data, other drugs, concerned about other defects. He focuses his analysis on those things that were most relevant in this courtroom.

Here are his 11 studies. Dr. Kimel used those 11 studies. And Pfizer, in it's literature review, used 10 of those 11 studies. And a sampling of the studies that Dr. Jewell did not use, Overlander (ph) no odds ratio or risk ratio provided. Margulus (ph) only reported on all SSRIs. Miles and McDonagh, because they have no original data.

It's not that he threw them out. As you'll see in his report, he discusses Miles and he's also discussed all of the meta-analyses in multiple testimony and deposition.

Now, I added these back in because I didn't think this would come up, but you saw the slide with all the societies, et cetera, and it's odd that we're here about methodology, and clearly the conclusions of the societies are uninformative if at all relevant, and that's not just because they're not in this courtroom and subject to cross-examination, so this is complete hearsay, and I would love to go take the deposition of whoever wrote this, but I'm not going to do that because I don't thin it's relevant. Why is it not relevant? Because you can look at it facially and see why. What did the American Heart Association do to access whether or not Zoloft was casually associated with cardiovascular birth defects?

Well first of all it looked at all SSRIs. Second of all it looked at all malformations, but those are errors that apparently the AHA are allowed to make. But most importantly they looked at Alwon (ph) and Luix. That's it. Those are the two studies they cite to for their conclusions. Here's what Dr. Jewell at this point looked at, and we're going to have more data.

So the American Heart Association, how Pfizer can stand up here and excoriate Dr. Jewell for his methods and not mention to the Court, well the AHA, they only looked at two when they made their decision. Or Otis, that's an organization that's right -- looking out for kids and birth defects. Well how many studies did Otis report on? Four. That's it. This is a 2014 paper, right? Could they have done, I don't know, any of those? How about the most important one according to Pfizer? Hubrix (ph), not even in there. Jimenez Solem (ph), huge, right? None of these get mentioned in the Otis paper, and they just look at those. And of course that's the conclusion you're going to reach.

So the societies are not here and subject to my cross-examination. The societies clearly are not as informed as the 30-plus page report

-- to 50 I think now -- before the Court, and have not done the analysis, haven't even bothered to look at the studies that Dr. Jewell considers key studies.

During the Fry hearing I had the opportunity to have a conversation with Dr. Kimel, and Judge Bernstein captured one -- the issues regarding this first step in the methodology in his opinion on Fry where he said, Dr. Kimel, the primary defense expert at Fry, agreed the appropriate first step in determining whether Zoloft is strategenic is to identify the relevant literature. That is Dr. Jewell's step. Dr. Kimel agreed that Dr. Jewell reviewed the appropriate literature. Quote, "Yes, I listened, so I certainly know Dr. Jewell and I looked at the same literature." In addition he also captured the fact that Pfizer's internal experts also looked at that same literature.

So we think that with the addition of the studies that were published since Dr. Jewell's report, which we'll discuss Berard, Furu, Wemocker, Refuse (ph), and the adjustment to Luix, and there is one new meta-analysis that we'll also discuss, but it does not meet Dr. Jewell's criteria for an inclusion, because it does not provide original data. I'll also demonstrate that is fatally flawed. Dr. Jewell will

at least.

So those are what Dr. Jewell considers to be his core studies as defined by his inclusion criteria, and as Dr. Kimel says appropriately included in the analysis.

So, I think that through step one we're in pretty good shape.

There's concern about overlapping populations, and again, this isn't something that Dr. Jewell ignored. Dr. Jewell applied a reasoned scientific approach to the issue of overlapping populations. And there are number of overlapping populations.

For example, in this list if you're looking just geographically Luix and Alwon overlap. Now Alwon has an update, it overlaps. Cowan and Reece overlap. Peers and Cornum (ph) and Jimenez overlap. In fact Furu tries to take all of them and throw them in a bucket, and it doesn't work well. Why? (Indiscernible).

So, Dr. Jewell is cognizant and an attentive scientific and he says, I don't intent to imply that the results from all these studies are entirely independent. It's important to determine whether there are relevant differences between the

studies that lead one to be strong than another or that differentiate them so significantly that the results should not be interpreted as simply the same study. Pfizer would like nothing more than to take Jimenez, Cornum, and Peterson and say, it's one study. And in fact they take that and throw it over into Furu and say Furu is actually the right now. Right?

There are blinders that you can put on when doing that. They don't pay attention to good science. Because what do good scientists do? You wouldn't just look at it and say, oh, all they're all from Denmark. You'd actually do an examination of the overlap, see if there's a difference, see if they used different methodologies. That's what Dr. Jewell did. His report is replete with why he did it the way he did it.

Now, Dr. Kimel in this courtroom actually testified, if you have studies that are looking at the same data, and Jimenez Solem was exactly the same population as Peterson, so you get the problem. It doesn't have to be 100 percent overlap, right? But if you have two studies that examine the same population and they overlap by 75 percent of the years, well in a meta you wouldn't include both those.

Okay. Let's take that at his word. You know, Dr. Jewell actually does a more in-depth analysis, looks at the method, sees if they would have included or excluded women in one or the other. Does one capture confounders better than the other? And does an analysis to see which study is better, beyond just looking at how many years. I mean I could do that. So, I did.

Here's Reece and Cowan, so these are the Swedish studies that Pfizer relies upon, because it has a .7 and a .7. Well they might act similar because if you look at the difference here you have Dr. Kimel's magical 75 overlap by years So, Dr. Kimel wouldn't include those two in his meta-analysis.

But when you look at the Danish studies what you see is some very different data. This is the years across which the study was done. This is the total study population, the size of this block. Cornum was done in four counties in Denmark. Peterson was nationwide but for a short period of time. Jimenez Solem was -- nationwide -- countrywide I guess is the right word, for a bigger period of time. Just one way to demonstrate that you don't lump all these together and say, oh, it's the same thing just to look at this pie. That's the total number in Cornum,

215,000. So if we assumed, counter to what the facts show, because Cornum has all these extra years here, but if we assume the years absolutely overlap Jimenez Solem has 633,000 additional pregnancies to look at.

Do you throw that out? Is that not relevant? That's not what scientists do, they don't throw out information. They look at the information and see if there's something important in that information that might inform their decision. How do we know that? It just recently happened.

This is a Refuse study that Pfizer discussed. It is indeed an update of Alwon. So it takes the Alwon data from 1997 to 2002 and updates it. Repeats this entire set of data and then adds data to it, much like Reece did in Reece Cowan.

In response to that there were some comments posted, and one of the comments came from a Michael B. Bracken (ph), a professor at Yale University who happens to be a consulting expert for GlaxoSmithKline and Forest (indiscernible). And Dr. Bracken writes something that is exactly what Dr. Jewell says in his report. And this was just written a couple days ago.

One strategy for evaluating which of Alwon's observations are likely due to chance is to

examine the new data to see if the associations are replicated. All right? That's a great idea. We have in Cornum and Jimenez we have this little population, we have all these additional women. If that's a three times risk let's check and see, back those women out if you can, and let's see if when we back out that earlier group can we confirm the associations in just that 633,000 women? So when Alwon Refuse 1997 to 2002 -- that should be -- oh, that's entire -- 1997 all the way to 2009, Refuse picks up all of those cases and controls and adds these new cases and controls. You can see that there's more information, but you could also do a comparison between these two just like Dr. Bracken says at Yale, and just like Dr. Jewell would say in this courtroom.

What do you find? Well when Alwon put Sertraline there's a .7, and in Refuse for Sertraline it's now gone up to 1.0. That's in the final study results. So wait a minute. You say, Refuse includes Alwon, so shouldn't it be .7, .7? Well it's not. So there's information there from the new women that are analyzed. There's information here in the additional years about this. And what is that information? Well to get from a .7 to a 1.0 what it tells you is that the women who were added to Refuse must have had an

increased risk of 1.2 to 1.3. That's the only way you can take a .7 and get it to a 1.0. When you include the .7 you add these women, you have to have -- be out here just as far to be able to get it to 1.0.

So what does that show? It shows that in fact the later data, what Pfizer just told you would be the better data captured because it's coming in later, and it's in fact true, they changed the capture instrument between these two studies, they started to capture data better in Refuse. There's Refuse capturing indeed an increased risk. Now it's washed out a bit down to 1.0 because it's also bringing forward the Alwon data.

So do you ignore this? Because that's what Pfizer wants you to do, they want you to throw out earlier versions of studies where you apply scientific method to and determine whether or not there's information in there that can be important to you as a scientist.

So overlapping populations does not mean you simply throw out earlier data. It means that earlier data needs to be looked at within the context of the question that is being asked and not ignored.

So Dr. Jewell's next step is to examine the associations. And just a reminder, that a

positive association -- this is not my language or Dr. Jewell's language, this is the reference manual in scientific evidence -- if a relative risk is greater than 1.0 the risk in exposed is greater than the risk in the unexposed.

Does that answer the question on casualty? No, everybody knows that, right, in this courtroom. There's a positive association. And what does it say? It could be causal. What else could it be? It could be chance or it could be bias, including confounding, just like Dr. Jewell's methodology.

These are the all cardiac outcomes in the core studies that Dr. Jewell reviewed. And you can see that the red ones would be statistically significant because they do not cross one or unity. And you can also see that the majority of the studies are on the right-hand side. Is that all you do, look at the first one and say, okay, we're in? No. But this is a starting point to examine the associations.

These are the all septal outcomes. Same facts apply. Significant ones, risk, and one down here that goes sub one, and Refuse, the recent one, which is 1.0, but as we discussed likely the newer data in Refuse is to the right of one.

This is just gathering the data, that's

all you're doing.

These are individual septal defects. I didn't have the patience to plot them. And again, ASD, which is a subcategory of the septal defect, which show -- the bold are significant, and you can see here ASDs all double and plus of the risk. VSDs and another septal defect.

These below the line are the ones that go in a protective direction. And to be clear on this, Dr. Jewell doesn't say that this is supportive of an increased risk, because the confidence intervals had 3.76. He's been asked that question numerous times and has made it very clear that what he's saying is -- and it's right in his report -- this is not consistent with my opinion; however, the confidence interval was wide enough to include these potential outcomes. So it's not necessarily (indiscernible), that's all. It's not that this supports and I win. That's not what Dr. Jewell does, they know that's not what Dr. Jewell does.

These are all of the other cardiac -- these are as reported in the studies. Dr. Jewell didn't twist or turn or do anything here. Dr. Jewell is not indeed a cardiologist. Dr. Jewell says, I'm not the guy who could classify these things, that's

not what I do. I am reviewing the classifications done by the experts in that classification, some of which we'll get to in a bit. I'm reviewing the classifications done by Luix, for what it may be worth, Mitchell, Alwon, Furu, and I'm reporting those as they define them, and I'm reporting the most adjusted outcome, because I'm trying to be conservative.

And these are the outcomes for the other cardiac defects. Again, increased risk above the line, some could say that 1.02 should slide down, .82 below the line. There's duplication in that. Dr. Jewell didn't just put the good ones up here and duplicate them. There's Alwon twice. He's looking at all the data, he's not hiding from the data.

So let's access those associations. There's a chance. At the beginning of this case that seemed like a big deal chance, and I don't know, maybe I've just gotten past it, but we should spend some time on it. Because the first thing you do is this is every outcome in every study. The red ones again are statistically significant outcomes. These are increased risk. Below here are the ones that are to the left of one and incompatible with Dr. Jewell's assessment.

So when you're looking at chance there are a couple of ways to go about it. When you're looking at chance within a single study it is true that one looks at statistical significance and the importance thereof.

So let's do that. Here are the statistically significant outcomes. And Dr. Jewell looked at those and said, okay, there's replication for cardiac, there's replication for septal in here, but you know, I understand that we're in the context of multiple testing and multiple comparisons. So let's take a deeper look.

The typical way Dr. Jewell will go about looking about multiple comparisons would be to look across all of these studies and make a conclusion that goes something along -- he'll do better work with this -- along the lines of yeah, look, you can have this finding, but by time you have this finding and then that finding and (indiscernible) one and then that finding (indiscernible) one, it becomes statistically impossible that they're chance. You're replicating across multiple studies.

But Dr. Jewell, because Dr. Kimel mentioned it frankly in his report -- his original report in this case, said, I'll do this Bonferroni

adjustment. And what Bonferroni does is it takes a P value of .05 and it says for each of the tests you're doing you have to make that P value even bigger and even bigger -- I mean, I'm sorry -- even smaller and even smaller. And Dr. Jewell applied that to the Jimenez Solem findings.

Now remember, I understand that Pfizer has concerns with the confounding by indications show in this study and other issues. That's not relevant at this stage, right? At this stage you're testing it for chance. We'll get to the confound.

When you test these for chance under the most conservative method that's out there, which is the Bonferroni application, all (indiscernible) survives, all septal survives, VSEs survives, and ASE gets pretty darn close. That P value is ridiculous, right?

Now, Dr. Jewell would not want to stand up here and say that's very, very, very, very -- you know, Dr. Jewell and P values, we'll get to that in more detail, but these do not make or break whether or not a study should be looked at. All right? Because according to Pfizer nothing except those studies should be looked at. Those are the only ones that matter because they're statistically significant, and

then let's pick those apart, let's pick apart Berard, let's pick apart Wemocker, let's pick apart Jimenez, let's say you can't do Jimenez and Cornum, because that's a nice limited universe. But look what you're ignoring when you do that. All of this information that's in here, because you picked some arbitrary point and said if it's not this we're (indiscernible).

Now is Dr. Jewell alone in that thought? No. This is -- now you've heard a lot about him. Here's his picture. Boston grad (indiscernible), discussing his points. None of my viewpoints can bring indisputable evidence for or against cause and effect hypothesis. That is an important issue. Nothing is dispositive, as Bradford Hill says in the same treatise, nothing is necessary and nothing is exclusive, determinative. You have to approach this with a scientific eye.

If it were simply P values and statistically significant or not I wouldn't need Dr. Jewell, I can do that through OpenEpi if it's not the generalized equation, whatever that is.

So he also says in the same -- next paragraph, no formal test of significance can answer the question. What's the question? What they can do, these viewpoints and significance, with greater or

less strength is to help us to make up our minds on the fundamental question. Is there any other way of explaining the set of facts before us? Is there any other answer equally or more likely than cause and effect? And what Dr. Jewell has included is that there's no answer that is equally or more likely than causal in this case, applying exactly this gentleman's methods. He says no formal test of significance can answer those questions. Beyond such test can and should remind us of the effects in play of chance, and they will instruct us in the magnitude of the effects. Beyond that they contribute nothing to the proof of our hypothesis.

Now that doesn't mean you throw them away, that doesn't mean that significance doesn't matter, it doesn't mean any of that. What it means is it's one of a number of factors that you put into a bucket when you look at the totality of the evidence, and based upon those factors and a scientific analysis of those factors, do you believe that any other way of explaining these increased risks that is equally or more likely than cause and effect? Clearly there's a disagreement on that in this courtroom or we wouldn't be here, but that sounds, if the methodology is correct, like a question for a jury.

The reference manual and scientific evidence does not limit the inquiry to only significant results. Epidemiologists have become increasingly sophisticated in addressing random error and examining the data from a study to ascertain what information they may provide about the relationship between an agent and a disease without the necessity of rejecting all studies that are not statistically significant. Exactly what Pfizer requests that this Court do.

The Matrixx case, which the Court has read about and cited to in its opinions. The law does not limit the inquiry to significance. The Supreme Court unanimously -- this is from the reference manual -- the Supreme Court unanimously rejected the claim citing cases in which courts have permitted expert witnesses to testify to toxic tort causation in the absence of any statistically significant studies. Any. That's the Supreme Court.

Is that the end all and be all? No. Allen Mitchell in his emails back and forth to Sandra Greenland (ph), this is the author of the Luix study, one of them. Let me reflect my personal perspective. So what happens outside of the courtroom in the real world when it's not an expert report? Let me reflect

my personal perspective that the slavish worship of the dichotomist P value is something we have fought fiercely, including with the journals to which we submit our work. In that regard I was delighted to see the Matrixx opinion noting the fallacy surrounding devotion to the P value. Allen Mitchell, professor of epidemiology and pediatrics.

Now importantly Allen Mitchell, actually in the emails you (indiscernible) with the New York -- with the New England Journal of Medicine saying, look, you're making too much out of this. I don't believe in what you're trying to reprint here. But the Journal won. But the scientists don't believe it.

And it's not just Mitchell, here's Sandra Greenland. We can all see exactly how Kimel used the information. He used it precisely for the type of dichotomy abuse you say you decry.

Lynn Rosenberg (ph), professor of epidemiology. You and Sandra -- to Allen Mitchell -- you and Sandra share the same views about statistical significance. It would be good to end what has unwittingly become a battle, and one way to do that would be to take up his offer and submit the views that you agree with to the Court, because that's what

Sandra asked Mitchell to do, and Mitchell to, as he -- as a scientist would want, said, I'm not interested in getting involved in the litigation.

Sonya Hernandez Diaz (ph), an author of a number of these studies, including the Hubrix study. Dear Sandra, I learned that in an amicus brief can be perceived as part of the litigation and I don't want to get involved in litigation. For her own correct reasons. However, I still agree with the methodological -- this is methods -- methodological principals, and would be happy to sign a letter to the editor saying so about statistical significance. And logic doesn't limit the inquiry to significance, because that's all you would look at instead of that.

Now we're not running from are statistical significance, there are replicated significant results in here for cardiac defects, there are replicated statistically significant results in for perseptal defects, and then there are all of these increased risks, the right of one. Is that chance? Because that's the question.

So Dr. Jewell will come up here and let you know why he concludes that chance is not explaining these. He's not alone, there are a number of study authors who conclude the same way, again, as

his report addresses it.

Is it bias? He looks at detection bias, one of those issues, because the concern is babies whose mothers were treated with these drugs, those babies end up in neonatal intensive care more than babies whose mothers weren't. So do they get looked at more often?

One way to address it was done in Cornum, restricting the analysis to severe cases so that you'd see them no matter what, and there was still an increased risk. As recently as a month ago Wemocker did it for detection bias. This by the way is a paper by the World Health Organization, the WHO, and says, stronger -- you'll see this result -- the association is stronger for severe CHD and therefore it's unlikely to be explained as detection bias.

Confounding by indication, the big one in the room. Dr. Jewell's approach is fourfold.

One, there's no evidence that depression causes cardiac heart birth defects, not one study anywhere.

If it's depression, why don't all the antidepressants show similar risk? Okay. Don't even bother looking at all antidepressants, why don't all the SSRIs show the same risk? They're all prescribed

for depression. So shouldn't they all be increased? Right? The class fallacy. Why is there no risk on later exposure and for studies that do restrict it to depressed woman? The difference is Hubrix, for example when Hubrix does her initial analysis of (indiscernible), I'll show this to you for Zoloft, it's a significant increase in 1.27. Once she restricts it to women who had a diagnosis of depression it goes down about nine percent. Exactly the same in Bond. When Bond looks at all women it's a 1.52, when she restricts it to women who have a depression diagnosis it goes down 9 percent.

So what's the impact of depression? Maybe nine percent. That doesn't account for doubling of risk, right? All it does is move a 1.9 to -- I don't know -- 1.6 or 1.7. That's all it can do. Depression is not erasing a doubling of the risk.

Proof that -- this is Yonkers, who is actually very involved in the industry and publishes this paper that that Pfizer cites often but doesn't cite this part. We can find no studies that link maternal depression to congenital anomalies in infants. And it's true, there aren't any.

The WHO study, just a month or so ago, the evidence that maternal depression increases

congenital anomaly risk is lacking.

Mulick (ph), I can take this out now I suppose. The evidence -- the absence of significant increased risk of various birth defects associated with the use of non-SSRI antidepressants suggests that depression is not the cause.

And again, Cornum, no increase for other antidepressants, no increase for previous SSRI users, no increase for those exposed to SSRIs after the period of congenital malformations would take place.

So Jimenez is a big one, obviously increased risk in women who pause, and you saw the graph up there, and I think that probably accurately describes how one could think Jimenez works. The key to Jimenez however wasn't mentioned in that graph, which is the paused group of women is first of all all SSRIs, it's not broken down by individual SSRIs. So it ignores what Pfizer calls the class fallacy. In other words, that increased risk is across all SSRIs. There's not Zoloft specific data.

But here's one of the keys in Jimenez. It requires women to restart their SSRI in the year after birth. And as one study author who looked at this same data in Denmark concluded, says, in

accordance with Jimenez we found an association towards an increased risk in the offspring of women who had used SSRIs before pregnancy and within one year after pregnancy. In other words, we got the same result for pause.

But you know what, we don't think it's confounding by indication. Why? Because there could be a much simpler reason. Jimenez assumed that these women have a mental illness without being exposed or in pregnancy, and the increased risk of cardiac heart defects indicates confounding by indication. However, it was likely that women who have experienced having a malformed child are more inclined to resume their use of SSRIs after pregnancy. That's why there's an increased risk in that group. Because it's more likely that women will restart if they have a child that has a congenital malformation.

There are no studies showing that depression increases cardiac birth defect risk. None, zero. How can it possibly be that that's not the correct answer to Jimenez?

Now, Dr. Jewell did do an analyze in Jimenez where he took the Zoloft exposed women that had a three times increased risk and he compared them to that all SSRI pause group, and he compared them

directly, because Jimenez didn't do that direct comparison. And when you do that direct comparison Jimenez actually gives you a 1.6 increased risk.

Hubrix. Dr. Jewell did do an analysis of Hubrix, and I want to show you what he did. This is in the Hubrix study, as I said, this is their original analysis, 14,000 Zoloft users compared to 885,000 women who didn't use an antidepressant. It shows a statistically significant increased risk, not adjusted.

Hubrix doesn't stop there, she goes to the next level down and she says, let's restrict this to depression. So when you take the depression notably Zoloft goes down to 11,000, so 3,000 some odd are using it for something other than depression, and the comparative goes to 180. And the odds ratio goes down to 1.16, as I discussed earlier. And according to conventional statistics it would have gone (indiscernible).

Dr. Jewell simply takes these 11,000 women, using only data that's in Hubrix, and he says, Hubrix provides me with data about these 11,000 women. What Hubrix provides me is data that says which of these women filled a prescription during the first trimester? Because they're all exposed to Zoloft

during pregnancy, and they're all depressed. That's a nice tight group. We have a group of 11,000 women who take care of all their concerns about confounding. You know, this group never took an antidepressant, who knows what's going on there.

This, women who are depressed and who have a prescription for Zoloft in their hands that will give them enough pills to take it in the first trimester, right? But there's a subgroup that is women who had enough pills to go into the first trimester who refilled their prescription or filled the prescription in the first trimester. And Dr. Jewell said, those women are more likely to be exposed. What if we take the women who filled a prescription in this 11,000, what if we took the women who filled the prescription and compared their risk to the women who had enough Zoloft but didn't fill a prescription, so they more likely stopped. That's all. And it's an analysis that's been done in a number of studies, including other Hubrix studies.

And all Dr. Jewell did was take a look at that, using numbers already in Hubrix, and compared the risk of the women who refilled or filled their prescription to those who didn't. Statistically significant, 1.87 increased risk with a P value of .02

in that 11,000 women population. That's pretty strong.

How can you get a better comparison? Every women in this entire pie was depressed. So there's no confounding by depression. Every women in that entire pie had a prescription for Zoloft within 30 days of pregnancy. These refilled it or filled it in the first trimester, and they have two times increased risk. Statistically significant. Yes, Dr. Jewell is actually pretty proud of this analysis.

So Gibbons (ph) doesn't like it. Professor Jewell has not conducted his new analysis separately for women who filled two or more prescriptions -- and he quotes to where it is in the paper -- which would guarantee refill. So in response to that Dr. Jewell did that analysis, because she works -- provides that data. And he took the women, the same 200, 442 who didn't fill a prescription in the first trimester of more exposed under Hubrix's analysis, so they likely stopped taking it. And he compared it to the 3,000 women who filled twice during the first trimester, four more times.

So there's -- as Dr. Gibbons says, guaranteed exposure here compared to these women who did not fill a prescription. What did he find?

Almost the exact same data, 1.88 instead of 1.87, and the P value as .047. Statistically significant.

That was at Dr. Gibbons' request, essentially. That is strong data to demonstrate there's a risk. Every women in there is depressed, every women in there has a prescription for Zoloft.

And this you didn't see when you saw the emails that led up to Dr. Jewell explaining his analysis to Dr. Hubrix, because her final email to Dr. Jewell was, hey, thanks for the clarification on what you're trying to do. I agree it's an interesting possibility, why don't I speak with the others in our group and assess what we can do from our end? She thinks it's an interesting possibility. She doesn't think he's nuts.

Now, Dr. Jewell took the Hubrix data, his analysis, and the Jimenez Solem data, and he did a little meta analysis of those two studies just to see what the results was, because he's an inquisitive scientist. And what does that show? When he combines Hubrix and Jimenez Solem data, the two studies dealing with confounding by indication. Recognize that? 1.8 increased risk, P value 0.008. Substantial risk remains after accounting for confounding by indication.

He also looked at other potential confounders, these are in his report. Smoking, comparable results. In other words, smoking didn't change the results. Obesity didn't change the results. I'm sorry, obesity is an independent risk factor, but when women who were obese also took an SSRI there was more than a doubling of that risk. So it's an amplification of the existing risk. And he also looked at other unknown factors. These are all straight from the studies that are the core studies that all scientists use.

So once you determine that bias and confounding are not in play, chance is not in play, you look to Sir Austin Bradford Hill, and again, it's a matter of good scientific judgment, not a matter of simple statistically significant or not.

Strength of association. All of these are statistically significant outcomes showing an increased risk between one and the mid threes. Dr. Jewell's -- Hubert's analysis is on here as well. A strong association.

Consistently. Are these consistent results? Yes, this Bond in 2014 says they're consistent. Sertraline -- our results were consistent for Sertraline from studies from the U.S., Denmark,

and Finland. Finland is not for Sertraline.

Now U.S., which would be Luix, might be in question, but that doesn't mean that Bond would change his opinion, because they're consistent within a number of different studies, and consistent with Bond's result, which by the way was not significant, according to Pfizer.

So Bond is saying I understand I have a non-significant result, but that increased risk is actually consistent with these significant results in other places. So, I believe my result to be correct as well. That's a non-significant result she's harping on. Pfizer's epidemiologists agree. When focusing on a specific defect a consistently positive association -- consistent, positive -- has been found for Sertraline exposure and all cardiac defects, especially (indiscernible). Lumped. Especially (indiscernible).

What do they rely on? Horner (ph). They also rely on Peterson, two Danish studies. Why? Because good scientists do that. They don't throw out information. They recognize the difference between the two studies. I think Pfizer study -- scientists pretty good.

This is what you look at for

consistency as well. Is there a consistent increased risk in that graph? Is there consistently a problem going on? This is two. That's all two and above. All of those are two and above. These are all 1.8's, 1.5's. That's an increased risk. This is a textbook by Sandra Greenland and Kenneth Rothman (ph) and it's considered one of the basic textbooks in epidemiology. We know it because it's also in Musix, Dr. Kendall's University of Pennsylvania in their MPH degree program, course syllabus, modern epidemiology. It's taught in almost every epidemiology class in the country. It is considered a learned treatise. And when assessing consistency Dr. Greenland, it would not surprise you, and Dr. Rothman clearly say, it is sometimes claimed that literature is inconsistent simply because some results are statistically significant and some are not. That sort of evaluation is completely fallacious. Even if one accepts the use of significance testing methods, the results from a set of studies could all be identical, even if many were significant and many were not. The difference in significance arises solely because of the difference in the standard errors or the size of the (indiscernible). That's how significance is treated within this context in the scientific world of

epidemiology. In the most basic textbook taught through the first year of every master's students.

Who else uses this methodology? Dr. Kimel uses this methodology. This is Pfizer's sad heart study trying to promote the use of Zoloft as protective against recurrent myocardial infarctions. And in this study the relative risk of death when using Zoloft or myocardial infarc was indeed protected .7. A problem, .23 to 2.16. It's non-significant.

So what does that mean in the world? What do you do with that result, do you throw it out? Dr. Kimel wouldn't throw it out. Because when Dr. Kimel was writing his later paper on this issue, Dr. Kimel cited to that sad heart study for Pfizer, also for Pfizer. In the sad heart study, a randomized trial investigating the safety and efficacy of Sertraline in patients with post-MI depression, there was a non-significant reduction in MI risk in the treatment group, although it was not powered to detect any meaningful reduction. In other words, the reason it was non-significant, he's implying, is because of the power of the study, you pick it up because it's a rare outcome, the results, which are statistically insignificant, are consistent with what we observed in the present study.

Now is there a danger to doing that? Of course there is. But is it what even Dr. Kimel does? You betcha, because you don't throw out information. You try to figure out if the information makes sense.

And lastly, specificity or what's called the lumping argument. And here Dr. Jewell very clearly in his report says, for the end points I adopted the definitions and classification provided by the investigators. I did not do my own, I'm not the investigator expert and I'm not reclassifying things. I did not independently modify or pull study results.

Now the grouping of defects is by the professionals, by the authors. This is the Jimenez Solem study, corresponding grouping according to the European Surveillance of Congenital Anomalies Classification System Guide 1.3. Every study reports grouped outcomes. Every study. In fact most of them actually look at major malformations over all. Why?

Here's the professionals, the experts in the field and what they say. The purpose of classification, in the sense we use it here, is to group together anomalies who share etiologic or clinical characteristics. There is a balance to be struck. Again, if you just look from the outside and

you say, oh, they're different, yeah, different, you can't lump them, if you just look there it looks like Pfizer is right, but you actually have to apply good science. There's a balance to be struck between lumping together heterogeneous sets of anomalies and splitting so finely that there are few cases in each group. That's what they do in the real world. And Dr. Jewell didn't independently lump or split anything. He used exactly what these experts say you should do. In fact Dr. Kimel during (indiscernible) said they did it correctly.

Did they lump or group in (indiscernible)? They did. Did they do it methodologically properly or improper? I think it was properly. Would it be proper to lump all heart defects that occur in children when they're born? It's not improper. Does not improper mean proper or is that different? It is proper. And I agree with this. Assume you look at the specific defects and treat those in the problem way. Which is exactly what Dr. Jewell did. He looked at the all party act and then he looked at each of the subcategories underneath and he's looking down through to see if there's some inconsistency, something that stands out and says, I've seen these increased risks in cardiac, but look

at some of these over here, there's no increased risk, something weird is going on. That's exactly what he did, what a good scientist does, what Dr. Kimel says is a good methodology, and it's exactly what Pfizer did. Looking at cardiovascular defects, look at the subgroup to see if there's significant information in the subgroup.

Biological plausibility, I don't know if that's still at issue, but this Court has already found that the methodology of our biological plausibility experts used to reach their conclusions about biological plausibility are generally reliable and you've allowed those opinions in. So Dr. Jewell relies on those biological experts.

He gathered the relevant information, he examined the associations. The associations he assessed them for chance and biased, and he concluded that their causal.

Thank you.

THE COURT: Thank you, Mr. Zonies.

Let's call the first witness.

MR. ZONIES: Plaintiffs call Dr. Jewell to the stand.

THE COURT: Right up here. It's the same red chair.

THE CLERK: Please raise your right hand and place your left hand on the bible.

DR. NICHOLAS PATRICK JEWELLL, WITNESS, SWORN

THE CLERK: Please state your full name and spell your last name for the record.

THE WITNESS: Nicholas Patrick Jewell.

THE COURT: Please be seated.

MS. YATES: Your Honor, we made a request for the slides, and we don't have them yet. It does make it easy to follow along, if we could get this set --

THE COURT: Certainly. Let's see if we can get the electronics settled.

MS. YATES: Thank you.

MR. ZONIES: If we could have five minutes, Your Honor, we could print them out real quickly.

THE COURT: Yes, of course.

MR. ZONIES: All right.

MS. YATES: Thank you.

THE COURT: Let's go into recess and get all settled.

MR. ZONIES: Thank you.

THE WITNESS: That was quick.

THE COURT: Stay here.

THE WITNESS: I'm going use the restroom.

THE COURT: Very well.

(Recessed at 2:00 p.m.; reconvened at 2:15 p.m.)

THE CLERK: All rise.

(Call to Court)

THE COURT: Good afternoon again.

UNIDENTIFIED SPEAKER: Good afternoon, Your Honor.

THE COURT: Are the electronics in place?

MS. YATES: We have hard copies.

THE COURT: You have hardcopies?

MS. YATES: We're going to exchange PDFs I believe so that we have it electronically.

THE COURT: That should be helpful, at least there's something in hardcopy.

MS. YATES: For now I can use this, Your Honor. Thank you.

THE COURT: Thank you. Please be seated everyone. And Dr. Jewell. Dr. Jewell, you may resume the witness stand, please. All right, Mr. Zonies.

DIRECT EXAMINATION

BY MR. ZONIES:

Q. Good afternoon, Dr. Jewell, how are you today?

A. I'm fine. Thank you.

Q. Dr. Jewell, could you state your full name for the record, please?

A. Yes. My full name is Nicholas Patrick Jewell.

Q. And Dr. Jewell, what do you do for a living?

A. I'm a professor of biostatistics and statistics at the University of California, Berkley.

Q. And how long have been a professor of statistics?

A. At Berkley, I've been 34 years.

Q. Thirty-four years at Berkley?

A. And then a few years before that at Princeton and then back in Scotland where I grew up.

Q. And Dr. Jewell, I've put up a slide that are your qualifications. Does that accurately represent your education in the early to mid-70s?

A. Yeah, starting from graduate school and forward, yes.

Q. And you mentioned you were in Princeton, what was your position at Princeton?

A. I was an assistant professor in the department of statistics at Princeton University.

Q. And then in 1982 or '83, did you start at U.C. Berkley?

A. Yeah, 1982, '81 to '82.

Q. In addition to your job function as a professor in the division of biostatistics, what else, if any positions have you held at U.C. Berkley?

A. Well, I was very involved in the academic senate there for several years and then was appointed vice provost for the entire campus working with the chancellor at Berkley for about six to ten years in the 1990s. And then I served in a similar function for the University of California system under the president of the university in the years 2000.

Q. Now, I'm calling you Dr. Jewell. Are you a medical doctor, Dr. Jewell?

A. No.

Q. And some might stand up in a bit and call you Professor Jewell. Do you have a preference whether it's professor or Dr. Jewell?

A. Neither is fine, but if you have to, either is fine.

Q. You have a doctorate. Is that correct?

A. Yes, I have a Ph.D. in mathematics.

Q. And where did you receive that Ph.D.?

A. From the University of Edinburgh, in

Scotland.

Q. And do we see that up here when you received your Ph.D. was it in 1976?

A. Correct.

Q. You are also the author of the book that's shown on the screen, Statistics for Epidemiology; is that right?

A. Yes.

Q. And can you tell the Court, please, what the nature of that book is?

A. Well, the book was based on a set of notes for a class that I teach in graduate school at Berkley, largely to epidemiologists and a few statisticians about statistical methods that are particularly applicable to epidemiologic studies.

Q. And that's actually a good point, Dr. Jewell, who -- what are your students typically -- what level of science are your students?

A. Oh, I have about 100 students a year take this class. About 10 to 20 percent of them are M.D.s or about to be M.D.s, about 10 percent are statisticians and the rest are usually other graduate students doing Ph.D. programs or master's programs in epidemiology and public health.

Q. So your teaching is focused on graduate

students?

A. Largely, yes.

Q. Is this textbook used outside of your classroom?

A. Yes.

Q. Do you have a sense of how popular it is?

A. It's a pretty good seller, actually, according to the publisher. They're hounding me for a second edition.

Q. In addition to that authorship, Dr. Jewell, you've authored approximately 160 peer reviewed articles, primarily in the field of biostatistics and epidemiology; is that right?

A. That is correct.

Q. And can you just give us a sense of the breadth of that type of publication? What kind of issues have you published on?

A. Well, largely I publish it on statistical issues to other statisticians and have less interest in publishing articles outside of my own field, because that's just my publication style. I contribute a lot to the field, but I prefer to write original research in my own field.

My papers cover a wide spans of topics because I'm kind of old now. I've been at this a

while. Largely in the 1980s, I devoted a considerable amount of my effort to statistical issues to get a handle on the HIV epidemic, which began in San Francisco in 1981 just as I arrived in California. And I probably spent ten years designing, implementing and evaluating studies as a statistician on HIV and that led to my long term interest in using statistics to improve and understand infectious diseases. So I've worked on SARS, I worked on Ebola last year. I'm working intensely in Dengue Fever now, so that's one major area.

On the flip side, I've also because of the methods overlapped to a large extent, spent a lot of time thinking about analyzing chronic disease epidemiology. That would be like heart disease or cancer. And in fact, this book that's on the screen is largely about observational studies and not about infectious disease studies at all, so that reflects a second aspect of my area of interest. And I'm also currently extremely involved in human rights investigations. I'm working in Syria at the moment trying to evaluate the civilian crisis in Syria and also in humanitarian problems in relocating children with their families in El Salvador. So those are my three current basic areas of interest.

Q. Now, Dr. Jewell, when you're talking about that, you're not actually going, showing up in Syria and trying to see what the situation is, you're looking at population based effects of various outcomes of various effects?

A. Yeah. The group I work with, the human rights data analysis group, takes data collected by people on the ground in Syria and assesses it and cleans the data and manipulates the data and then averages it in a way to provide information to the United Nations about the state of civilian casualties in Syria specifically.

Q. So in doing that, Dr. Jewell, do you -- is it required that you, in fact, do a deep dive into the data, understand it well to be able to interpret it in some way?

A. Yeah, it's often with a lot of colleagues, of course, too, not just me.

Q. And Dr. Jewell, in this case, we've asked you to come before the Court and discuss the studies related to Zoloft and cardiac birth defects. Is that right?

A. That was my charge, I believed, yes.

Q. Is this something that is in any way novel or new to you, examining data for cause and effect?

A. No, in fact that's what I spent my whole life essentially doing is trying to understand causation. In fact, the book that's put me off the second edition of this is just coming out and it's called Causation, so I just spent the last year writing a book on statistical methods to understand causation, largely informed by my experience in exactly these kind of situations that this case itself is an example of.

Q. And that's a book that's being prepared for publication?

A. Yeah, it's in press right now.

Q. Dr. Jewell, in your work in this case, were any of your methods in any way, shape or form, new or different or unique compared to your day to day work?

A. No.

Q. Your publications, I believe I mentioned one of them about statistical methods, you have publications, for example, looking at the statistical method that Dr. Berard utilized in her study. Is that right?

A. Yes. A graduate student I taught at Princeton actually was the co-inventor of that technique that Dr. Berard used, so I was very familiar with it and I've had graduate students who worked on

that topic. In fact, I'm teaching that topic right now, this fall in Berkley, so I was more aware of the issue there than I wish I was.

Q. And is that a -- your work on that statistical process, is that a well accepted statistical process?

A. Oh, yes. It is now, it's well studied.

Q. In addition to your publications, you've been the editor of a number of journals and I've put some of those up here. What does it mean when you're an editor for a journal such as the journal of American Statistical Association?

A. Well, that's the premier statistical journal for the United States for people both in industry and academia publishing an area of statistics. There are actually two co-editors, because it's such a large journal. Between us, we handle about 7- or 800 submissions a year and the editor with a team of associate editors determines which papers will be published or not and provide advice back to the authors.

Q. So in that role, Dr. Jewell, do you have the occasion to review studies, review the methods used in the studies, see if the methods were appropriately applied and to critique the studies?

A. Well, I do. As the editor, I usually farm that work out a lot, so I'm usually reading someone else's review of those very questions and making the final judgment. There's one there I'm the associate editor of the most preeminent British journal in biostatistics called Biometrica, there I'm doing more of the evaluation myself. I must get asked many times a week to review articles for the medical or clinical or epidemiological literature with regard to statistical issues in those articles.

Q. And when making that review, Dr. Jewell, are you in any way hampered by the fact that you're not a medical doctor or if it's a review about HIV that you're not an infectious disease medical doctor or is your job similar to what you did here?

A. Well, usually statisticians work hand in hand with subject matter experts like medical doctors or infectious disease specialists so that the data itself that's being collected is being collected with that insight already there. The statistician is not defining conditions or telling people how to measure things because we're not trained to do that. So we have to work in research teams. It's one of the things I enjoy the most is actually working in a team of people, each of whom is an expert in their own way,

each of whom contributes important information and that's the only way you can get good science. You can't have statisticians running around on their own, they have to rely on subject matter experts and I've done that my entire life.

Q. And in your analysis and work here, Dr. Jewell, who were the subject matter experts that you relied upon?

A. Here I was dealing with Extent Literature or literature that's already written, so I wasn't involved in designing or implementing my own study, in which case I would have had to have, obviously, a team of perinatal epidemiologists or cardiologists or medical experts. I would needed to have database experts who knew where we could get information. But here, I was dealing with the work that had already been done by other research teams. And so I was relying on their expertise at face value that when they classified events in a certain way, I can certainly read what they did, question it, but I did not try and invent anything new, because that's not my area of expertise.

Q. If you were to invent something new, if you were to reclassify some of these outcomes in some different way, would that require a much larger team

than just you to work on that?

A. Well, it might if it was to make sense, yes.

Q. If you had felt the need to do that here, is that something you would have done?

A. Well, in litigation, I'm a little bit -- usually I'm signing a confidentiality agreement, so I actually work on my own and don't feel that I'm at liberty to discuss the details of the case with experts surrounding me. Obviously, as I said, it's one of the things I enjoy the most is interacting with teams of medical experts who know a lot more about the subject matter than I do. They don't know the statistics sometimes as well as I do and that's why you work as a team.

Q. And Dr. Jewell, is it fair to say that the authors of the studies were part of your team here? In essence, they've done the ground work?

A. In a sense, I was treating it that way that I was taking their data. I did not have access to raw data on any study. I was taking their data at face value and their analysis at face value. That's in part why I restricted to peer review literature, because at least someone else had looked at it to some extent.

Q. And Dr. Jewell, the final one says Editorial

Board of the Proceedings of the Royal Society B. Can you please tell the Court what that is?

A. Yes. This is a British organization, the Royal Society, probably the most prestigious scientific organization in the UK. And they publish academic journals and this specific one is the one dedicated to the biological scientists and I think I may be the only statistician on the editorial board. It's mostly biologists, but I do handle papers there that come in that have a major statistical part to their work.

Q. And would that be the same Royal Society where Bradford Hill gave his address?

A. No. Bradford Hill gave his address to the Royal Statistical Society.

Q. Okay. Thank you.

A. Not quite such a prestigious organization.

Q. Dr. Jewell --

MR. ZONIES: May I approach the witness Your Honor?

THE COURT: You may.

BY MR. ZONIES:

Q. Dr. Jewell, tab 1 of this binder has your report that you prepared for this litigation.

A. Thank you.

Q. And behind the report is your curriculum vitae. Is that as of the date of the report, at least, an updated CV with additional listing of all of the papers you have published, other editorial positions you've held and more of your experience in detail?

A. Yes. It's up to date as of the time I submitted the report. It's a little bit longer now.

Q. And so you have additional published studies since then?

A. Well, it doesn't mention the new book, for example.

Q. And also it has attached to it, a history of testimony in the past four years. Have you been past as an expert witness before and approved as an expert witness before in this context, in litigation?

A. Yes, I believe so.

Q. You've acted as an expert witness before. Isn't that true?

A. That is correct.

Q. Do you know offhand, how many different litigations that might be?

A. During my life?

Q. Or even if we look at the past four years, for example, it says that you were an expert witness

in the Depue hip (ph) cases. Is that right?

A. That is correct.

Q. Did you go through a hearing similar to this Depue or have a Daubert --

A. No. I was only deposed on that a few times on that case. I don't believe there was a Daubert hearing.

Q. Have you been subjected to a Daubert hearing before?

A. I have, yes.

Q. Have you been subjected to one in this courtroom?

A. I think it was in this courtroom, yes. It's a while ago now.

Q. It may have been on a different floor. I can't remember.

A. I can't remember.

Q. Have you passed Daubert and/or you may not know these names, Frye scrutiny in other litigations?

A. Yes.

Q. Have you also passed Frye scrutiny in this very litigation?

A. Yes.

Q. In this city?

A. Yes.

MR. ZONIES: Your Honor, we would offer Dr. Jewell as an expert in, as his book says, Statistics for Epidemiology.

THE COURT: Thank you. Would you like to cross-examine?

MS. YATES: Not at this time, Your Honor.

THE COURT: All right. I understood that there was an objection to his qualifications as to causation.

MS. YATES: Correct. So don't object on the mathematics statistical part, but what he then does with those opinions, I -- that sort of takes it to the next level, Your Honor.

THE COURT: It does. Well, he did respond to some questions, but you can defer. I'm going to admit him provisionally now as an expert in statistics and he is qualified to testify in this matter and you may proceed.

MR. ZONIES: Thank you, Your Honor.

BY MR. ZONIES:

Q. Dr. Jewell, you were here for the opening statements this morning and part of this afternoon?

A. I was, yes.

Q. I'd like to touch on some of the topics that

we discussed and make sure that I captured your thoughts on that correctly in my opening. One of the issues that was discussed was your expert opinion in Prozac. Do you recall those discussions during opening?

A. I do.

Q. Dr. Jewell, are you also designated as an expert witness in the Prozac birth defect litigation?

A. Yes, that is my understanding.

Q. And have you been deposed in that litigation?

A. I have.

Q. And written a report in that litigation?

A. I have.

Q. And it's probably now your understanding, if not before that that report has been provided to Pfizer as well? Is that right?

A. That is my understanding, yes.

Q. Pfizer, in its opening, Dr. Jewell, discussed one of the methodological concerns that it had which was that in Prozac you relied upon meta analysis when doing your expert report and here you chose to rely upon primarily original data. Can you please describe for the Court why those decisions were made? Why you made those decisions?

A. I think it's a little overstatement to say I relied on the meta analysis is the Prozac case to form my opinions I certainly looked at meta analysis more deeply there, in part because one of the major meta analysis was done by Eli Lily themselves, by the manufacturer and there was no such equivalent meta analysis in the Zoloft case that Pfizer was willing to carry out themselves. I just didn't have that. It doesn't exist to the best of my knowledge.

So that's, I think a little bit the difference in the first place. I had a manufacturer meta analysis on one case and not the other. There were meta analysis that have already been discussed this morning, carried out in the Zoloft case, some of which, if not all of them, also looked at other SSRIs, including Prozac. And you have to look at the data separately for each of the drugs because the data looks differently in those meta analysis, and specifically in this case for Zoloft and for Prozac. So you can't use a single statistical tool in all situations blindly as if it will give you interpretable results, ignoring what the data itself is telling you about whether the tool is valid or not. You have to look and see this is a screw, maybe not a great idea to use the hammer here. And that's exactly

what I did for both Prozac and for Zoloft. I looked at the same meta analysis, using the same studies, albeit looking in this case, these two different exposures. Looked at what the data said about the information and how it varied across studies and then on the basis of that made my interpretation. I think that's the best way I can describe why there were differences and how I came out of those looking at those meta analysis.

Q. Now, Dr. Jewell, I put up this glass of wine to describe heterogeneity and probably didn't do a great job on it, but I do want to put up the Miles and the chart for Miles that shows the objective evidence of heterogeneity for a sertraline as compared to Prozac. And then if you could explain for us, also McDonagh, which reflects the same. If you could explain to us what is heterogeneity and what is a good way to describe why that could call into question results?

A. Well, meta analysis is a tool used essentially to average results across many different studies. It's used when we have a question, no single study probably is definitive in its own right. That's a very common phenomenon in epidemiology . Different authors and different populations start

studying the same question and at some point in time somebody wants to collate the information and in a sense provide the average summary of what do all these studies mean. And we have examples of that in this case and I've testified in this very courtroom as you've pointed out of doing that for randomized clinical trials, which is a much more reliable situation to apply meta analysis for reasons I could explain if asked.

So here we have a whole series of observational studies and people have tried to average or summarize them. The first thing that's important, I think everyone agrees that you want to get high quality comparable data into the meta analysis and both Mr. Cheffo and you have referred this morning to inclusion exclusion of which studies you include. That's important and certainly is worth discussion. But at the base of it all, meta analysis is about averaging and I love averaging. I've made my living on averaging. That's what statisticians do, right? That's what you see a number of at bats and you wonder what's the average, so we grow up learning how to do that. But we also are taught very early on that sometimes averaging is dangerous because it obscures variation.

Now, I know in this courtroom I'm surrounded by friends, on both sides of the house, good friends. I've seen you all so many times. I assume no one here would want to do me harm, but suppose you did and you decided that you were going to do me in and just stick my head in an oven this afternoon after we break, turn the heat up to 500 degrees Fahrenheit and you think that ought to do it, give him a little time to cook. But then you think, well let's be sure, let's also at the same time freeze his feet at minus 400 degrees Fahrenheit. I'm a goner, we all know this.

But just as I'm dying, I look up and say, I'm a statistician. If I average the temperatures, I'm just fine. My body temperature is perfect, thank you. But we all know the fallacy there, the point is that averaging in that case is hiding in this case two extremes. So you don't want to do a meta analysis blindly where one study has a relative risk of .5, maybe it's a very good study. And you have another study, equal weight, equal strength, that shows a relative risk of 2 and you're tempted to say, well I've got these two inconsistent studies, let's average them. But I just told you, you all laughed, that's stupid. You realize that, because you got a relative risk of 1 and you say there's nothing going on, but

that's not the truth. The truth is there's something seriously bad going on in one study and seriously protective in the other and you can't hide from that. In fact, to hide from it is to make a statistical error of letting averaging obscure the variation.

That's exactly what's going on in some of these meta analysis. There is so much heterogeneity that the average loses its meaning. It's not technically that averaging can't be done. I can do a meta analysis. Even you can do a meta analysis, Mr. Zonies. I know you can. It's easy to teach, it's easy to do. Give me an hour and everyone in this courtroom I can have doing meta analysis tonight, very well. But it's not the doing of it, it's making sure you do it right and interpret the data and heterogeneity of different studies has got to be looked at.

Sometimes there are differences in very large studies, very good studies because the populations are different. That's possible. It is possible, some unlikely, but it's possible that a drug might be doing harm in one place and being protective in another, so you certainly would look at that possibility. Are there characteristics of a population that allow you to understand this

heterogeneity. More likely some studies suffer from some biases because they're in different populations than other studies. You ought to take that into account.

Maybe the studies that show the relative risk of 2 are -- have a strong bias in them and the one that's at a relative risk of .5 didn't have that bias. That's going to influence. I'm not going to take those two studies and throw them into a meta analysis at that point because now I know something about them. In my view, that is the best way to approach meta analysis and not just if I use your analogy, not just say I want to teach you about red wine and white wine. Gee, let's just cut the corners and just mix them and give it to you because the averaging is not going to tell you the truth of what red wine tastes like and what white wine tastes like. They're heterogeneous.

Q. Does that mean there's no way to determine whether or not there's a causal association? Do we just toss it out?

A. No. I mean, it means that you have to go deeper than just the mindless application of a meta analysis. As it turned out in Prozac, there's far less variation in the results than there is for

Zoloft. And the slides you just had up there for both Miles meta analysis and McDonagh pointed that out, but these people were not statisticians. They didn't know what to do. They did what I would teach you to do tonight. They ran the meta analysis, reported the results, but then come, of course, to these kind of not very helpful interpretations because they've just averaged high temperature and low temperature and said it's perfect and that's not what the data is saying. You've got to listen to the data itself. And you can see that here in this slide, you can see there is the Sertraline, the heterogeneity I won't bore you with the description of the I squared and what it means, but it's a measure of how much heterogeneity it is. You can see with Fluoxetine, zero percent heterogeneity reported by McDonagh, but Sertraline 68 percent heterogeneity. And you can see up there at the top, we're not talking about any SSRI, 84 percent, that's why we don't want to lump them all in in some big litigation of let's look at all SSRIs together. There's too much variation and it's clearly different here for Prozac and Zoloft and that's why I did something clearly different in my interpretation and use of these information.

Q. Now, meta analysis in the world of

statistics, is it a fairly recent phenomena? In other words, before meta analysis, would people just say, oh we can't figure this out or would they do essentially what you did, which is the sometimes harder way to go about it?

A. Yeah, meta analysis is not recent now, but it wasn't around when I was in graduate school. The tools probably started being publicized maybe 20 or 30 years ago. It remains a somewhat controversial field because of this difficulty in knowing how to use it effectively, but it's been around for, I would say 20 years or so, but it has to be used carefully. Do not use a meta analysis to hide variation, that's a mistake. And to use specialized statistical tools, because statisticians have worried about this like the so-called random effects model is one way to allow for variation, but then every single document in this case that I've read, which contains one of those analysis has been misinterpreted by every single individual as a measure of an effect. Just like saying my average temperature tells you what my whole body feels like. Every single one has been misinterpreted, because it is a little tricky when you have to try and deal with this heterogeneity.

Q. So Dr. Jewell, one of your concerns that you

discuss in your report with the meta analysis and in particular originally Miles meta analysis was about the inclusion, exclusion criteria, which studies and which end points were looked at. Is that right?

A. That is correct.

Q. And you have a quote in your report from Dr. Kimel in his textbook discussion how that can have a huge impact on the outcome of the study. Is that right?

A. I'm sure he would say that still, yes.

Q. And while you were doing your review, one of the things that you noticed about Miles was some concerns you had with the studies that were included or excluded. Is that right?

A. Yes. I read this and I think it looks like you've highlighted it there. An exclusion criteria was used to say we're not going to look at studies if in the control group -- these are people not exposed to an SSRI and to Zoloft specifically -- if in the control group, unexposed group, if they were exposed to the drugs, other anti-depressants it says right here, we're not going to put those studies in our meta analysis. If I read that correctly, it says if some others in the control group were exposed to other anti-depressants we're not going to include them. And

that puzzled me because in the Miles paper -- there were for Zoloft, there were only four or five. I could see that that didn't quite match, because I had now gotten fairly familiar with these articles and so I was puzzled by that when I first wrote the report.

Q. And in particular, here are the one, two, three, four, five studies and one of them is Alwin (ph) and this is from Miles; is that right? The (indiscernible) plot of meta analysis?

A. This is the summary, yes.

Q. And your slide says two of the five studies include mothers who took other antidepressants in the control and you've excerpted out, in fact, from Alwin?

A. Correct.

Q. Exactly that effect?

A. Correct. This was behind my puzzlement about well it sounded like Alwin should have been excluded, just so I understood, as we just said, how important that is to understand where the author is coming from in terms of which studies they put in or not.

Q. And that's how you wrote your original report, right, was that you had concerns with that?

A. That is correct.

Q. In addition to your concerns with the heterogeneity in the Zoloft (indiscernible), right?

A. That is correct.

Q. That was before you wrote your Prozac report, right?

A. That is correct.

Q. And you're aware Dr. Jewell, that Pfizer's lawyers then wrote a declaration or an affidavit of one of the authors of the Miles study that Mathew Large?

A. Yes, I was presented this, I think right at the first deposition on the Zoloft case with this affidavit or declaration from the senior author of the Miles meta analysis saying in fact my interpretation was incorrect and what they had written, by inference, was also therefore incorrect. That in fact, the only excluded studies if all the women in the control group were taking some other anti-depressant and this is an excerpt, I think from that declaration.

Q. Which was inconsistent with the study itself, which said only some mothers?

A. Yes. It actually flatly contradicts what it says in the paper. I believe Dr. Large offered to write and correct this in the literature. I don't believe that has happened yet, but my understanding is

he himself accepted it was not -- these two statements were contradictory.

Q. So Dr. Jewell, you said there were five studies in the Miles for all cardiac and here are the five outcomes or those were the ones chosen by Doctors Large or Miles?

A. If by that team that is with the five included in the meta analysis, yes.

Q. Does this give you some concern that these were the only end points they looked at?

A. Well, this is the all cardiac outcome that has been pulled out here. That was the grouping that they selected to report, not what I -- this is from their paper, this information.

Q. Did you examine each of these outcomes in your work?

A. There wasn't a single outcome reported that had Zoloft specific data on a cardiac outcome that I did not put in my report.

Q. Did you examine them in more detail than just plugging them into the software program and running a meta analysis?

A. I did. I've looked at all of these papers now in great detail.

Q. There were two additional meta analysis, one

McDonagh and one recent Wang; did you have concerns with those as well?

A. Well, they suffer from very similar criticisms. In fact, all of these analyze a very -- a relatively small subset of the existing studies. Someone had a slide earlier maybe in your opening where you had all the studies listed, which is in my report and you may be added a few of the recent ones. And you could see it filled up the page. Here you can see that the Miles meta analysis looked at only five studies. This is the AHRQ where the lead author was McDonagh. Seven, so none of these meta analysis have looked at the data that you and Mr. Cheffo described this morning. They're missing -- there's no Jimenez Solem here. There's no Hubrix here. These, as Mr. Cheffo points out, two of the largest studies ever done, they're not included. So anyone making a conclusion about Zoloft on the basis of these meta analysis is now deliberately or not specifically ignoring considerable information that as Mr. Cheffo pointed out, we've gone to great lengths as scientists to collect to shed light on this question. So irrespective of the methodological issues, which I believe there are in spades, these meta analysis are just not comprehensive enough anymore.

Q. And Dr. Jewell, the AHRQ actually looked at Cornum and Peterson, two Danish studies in one of their meta analysis. Is that right?

A. They did. And they also looked at Colin and Reese Colin, which as you yourself pointed out, Colin is essentially completely subsumed by Reese Colin. They should not have been in there together in a meta analysis because one is contained inside the other and there is overlap between Cornum and Peterson also.

Q. So this is the most recent meta analysis the Wang (ph) meta analysis. Does this reflect a complete review of the literature to determine whether or not there's a causal association between the use of Zoloft and cardiac birth defects?

A. Well, the publication of this journal, because I was now knee deep in Zoloft, this just led me -- I'm going to say the Scottish word if you'll allow me -- gob smacked. Is that an American expression? She probably understands. That just means I was just stunned. Here we are 2015. I've been through three or four depositions, hearings, I've reviewed the literature, Dr. Kimel has spent a considerable amount of his valuable time and here comes a meta analysis, three articles. It includes Colin and not Reese Colin, which is the update, so

that's sort of a no, no. It does include Hubrix, terrific, which was in I think 2014 very recently. There's nothing about Jimenez Solem and all the other European data other than the Swedish Colin study, completely ignored Colinun (ph), which is Australia, nothing from the UK, nothing else, none of the other papers. And so this is, to me, just ludicrous, why these three, there was no explanation in the paper. There's no scientific rationale behind that. This paper, I trust you on both sides, you should just completely ignore it. It adds nothing beyond what was in those three papers, which we all looked at in detail and it's just a very sorry example of what can go wrong with publishing spurious meta analysis.

Q. These are the studies listed out that each of those covered. Did you do an in depth review of all of the outcomes on cardiac for all of these studies?

A. Yes. I didn't look at Overlander (ph) that much, which McDonagh raised that, because of the reasons you mentioned in your opening, but I did look at all of the others. I read all the original articles.

Q. So in your expert opinion, Dr. Jewell, what is the better way to determine the question before the

Court in this case, whether or not Zoloft is causally associated with cardiac birth defects? To look at these studies in a meta analysis setting where there is heterogeneity and questionable inclusion, exclusion criteria or to do an in depth review of each study, look at its internal biases, including confounding by indication, and determine whether or not that association exists?

A. Well, I clearly believe I did a better job than these meta analysis, partly because just in the timing. With Miles, he couldn't put in Hubrix, for example, so that was not a flaw in itself, but now it makes it outdated because we've got a new study that provides a lot of information. So these studies should not be relied on. I'm kind of taken aback when the Pfizer indicated this morning something I didn't know that FDA is relying on Miles for its label decision, because that clearly doesn't validate Miles. What it does is invalidates the FDA's conclusion because it's based on old, outdated data. And no scientist would ever want to do that.

Q. It's based on these five.

A. These five studies, yes. I'm missing some very important ones that will possibly talk about at length.

Q. So these are the end points you've --

A. Right. These are all the end points, including all cardiac and subcategories for all of the studies, the dozen or so studies. So this goes way beyond anything that's in any of those meta analysis.

Q. Now, there were some discussion about Dr. Berard and generalized estimating equation models. Are you surprised knowing that Dr. Berard's study and her statistician, knowing that they used generalized estimating equation models, are you surprised to see that there is a difference in the confidence interval if you put the numbers into openepi (ph) or you actually run the numbers to generalized estimated equation models.

A. Yes. That's the whole point of running the more sophisticated analysis, which correctly allows for the fact that you're looking in her study on multiple pregnancies from the same women. And multiple pregnancies for the same women tend to be correlated. They're not independent replications, if you want, of an outcome or a trial of seeing a pregnancy and seeing what its outcome is, because it's from the same mother and often the same father.

So statisticians develop these tools, one of which is GEE, a different tool from what Furu (ph)

used with a similar situation, though they at least recognized you also had to do something different than what software like openepi would do. You have to use more sophisticated software to assess the variation. It doesn't change the point estimates and that's why when I was in Frye hearing asked to reproduce the results on the stand, I got the same point estimates. When Dr. Kimel did it, he got the same point estimates. When I checked them again in my hotel room, I got the same point estimate. The software doesn't change the estimate, but it says the variation is different than what you would get from the crude calculations that were done in Dr. Kimel's report and were put out this morning in Mr. Cheffo's opening.

In fact, I initially saw that myself and tried to find out -- I didn't see initially that there was this multiple pregnancy issues, but when I went back to the hotel room after the Frye hearing, I read the Berard paper and it says right in the Berard paper, to her defense it says right in there, our data has a lot more multiple pregnancies and we've had to use this more sophisticated software. I'd love to be able to check it, but as I testified and as Mr. Cheffo pointed out, I said, you can check that calculation without the actual original data.

And in fact, Dr. Berard did check it and said it's correct. I have no way, of course, verifying that personally, but it's not an issue -- so the issue here is not of a mistake necessarily on openepi (ph) being different, that's completely irrelevant. I pointed this out at my deposition. I told the Pfizer lawyers specifically the questions to ask and to relay to Dr. Kimel, that this is not the point. This generalized estimating equation approach is a more sophisticated method and it's going to take a lot more work to verify the results. It would take the original data and no one has done that, other than Dr. Berard's statistician and she claims the calculations were done correctly. I have nothing more to day at this point.

Q. Do you have any reason, whatsoever, if you had never heard of Dr. Berard before, never known that she was attacked in this courtroom, would you have ever questioned that outcome in any way?

A. No. I don't know her personally, of course, and I don't have any reason to second-guess the published results in peer review literature of any of the authors until a mistake is brought to our attention. That's the small error in Luix (ph). Sure, then it's important to correct it, but I have no

-- a (indiscernible) or a reason. She said it's a more sophisticated that's been done. The data is more complicated, you know, absent someone independently verifying it, which we would have to do with all these papers, in a sense, I have no way of knowing. I take it at face value at this point.

Q. Well, in fact, would you love to get your hands on the Hubrix data?

A. I would love to get my hands on the raw data. Yeah, I've asked for it and I was told I couldn't get it by the author.

Q. And is that similar to any of these analysis, if you had the time and I had the money, wouldn't you love to rerun all of these and see what you find?

A. I can spend a considerable amount of my life doing exactly that, but normally I can only get the data when somebody does it in litigation, because I can't get it as an independent scientist.

Q. And as Dr. Hubrix said, when she said I'd love to give you my data, but we're subject to an agreement that doesn't allow us to release it, is that actually fairly common?

A. That's very common and it's common in situations like her, where she was dealing with

Medicaid data where there's confidentiality arrangements. When you're dealing with a manufacturer, there's usually intellectual property issues, which means they will not release raw data from studies or trials, so I rarely get it, except in litigation, but then I do spend a lot of time reproducing individual results. That's an important task.

Q. If Pfizer had decided to do one of these studies, you would hope that they would provide the data from that study to you, right?

A. I always hope that people will provide the data, because I'm a big open data person.

Q. But from where you sit, Dr. Jewell, has Pfizer ever bothered to do an epidemiological study about this very important question?

A. well, I don't know if they've tried. I haven't seen any published studies sponsored by Pfizer that I'm aware of.

Q. But you are aware of only because of your work in the Prozac litigation, that other manufacturers certainly have done that, correct?

A. Well, they have, yes.

Q. Lastly on this initial topic, Dr. Jewell, the New England Journal of Medicine at your request by

sending a letter asking them to take a closer look at their logistic regression analysis that they provided to us. Can you explain to the Court please what your concern was with the regression analysis that they supplied and said was the regression analysis that was used to reach the results in the original paper?

A. Yes. I may be giving you more detail than you want, so please stop me if I am. My understanding, I was in Philadelphia in July eagerly waiting to be here and then was sent home because of this correction and the confusion around it. And I was handed some information that the authors had by e-mail indicated that there was an error that a 1.2 lower bound for confidence interval associating Zoloft with all septal defects was incorrect. It should have been 1.0.

It's a slightly odd error to make. I can certainly understand 1.02 becoming 1.20, I've made that kind of mistake many times, but anyway, I didn't know. That was the issue. There seemed to be more concern than is really warranted from a statistical point of view in whether it was 1.01 or .98. I don't think there's a statistician in the world -- well, that's -- let's not be sweeping generalizations -- there's very few statisticians who really believe that

and we saw some quotes this morning that it would make any difference to your interpretation of the information, given the context, if we had only one study.

If we were here and Luix was the only study that we had information on regarding Zoloft and cardiac defects and in specific, septal, that becomes much more important. I think it becomes important to the Court. It becomes important to the statistician. This is the only information we have and do we have enough information to be definitive with regard to causation. A statistical significance in the context of a single study is important. It's important in efficacy studies. FDA requires statistical significance, but that's not the context I was in, in July.

I was in the context where Luix was one of a dozen or so studies and this was a subcategory of the all cardiac, it wasn't even a transcription error on the all cardiac results, so I certainly wanted to know and was pleased to get the correction. But whether it fell on one side of 1.0 or not, I think is reflecting that in this case, Mr. Kimel or Dr. Kimel and subsequently Pfizer this morning, if I can use the words of Bradford Hill, he would say they were

specifically grasping at shadows and losing the meaning. It was not -- they were just down there at that slavish covering, 1 or zero.

It really makes very little difference. I reproduce my forest plot with the change in and without and I guarantee you I can show those two forest plots to a million people and not one of them could tell the difference between the two in a minute or two, because they look identical. It's a tiny change in a sea of evidence. So from that point of view, that point people were focusing on whether it was one or zero, so I said, let's just look at the output.

Dr. Mitchell originally refused to say what it was, so I think somebody went and got the information in the output. Great, so now we could know .0498 was the P value and the lower bound I think was 0.98 or something like that, just clipping 1. But in providing the output, I looked at it to see that that corresponded exactly with what was reported in the paper and it didn't. They actually had different variables in what they reported. What they had done, I think in July, suddenly in the middle of their summer vacations, they've gotten this flurry of interest in a four or five year old paper. They reran

the analysis as best I can tell. And I was concerned, well, are you rerunning something different from what was in the paper and we asked them.

And I think I just learned yesterday that in fact, the output they provided did not quite correspond with what was in the paper. So they're having, I think, to publish another correction. They're now going back and changing a five year old paper to report an analysis that was done in July. As an editor that would make me a little bit nervous, but that seems to be the gory end to a really kind of senseless discussion.

Q. Well, Dr. Jewell, let's talk about that. What was -- do you recall what the odds ratio estimate was for that?

A. The odds ratio was 2.0 rendered to one decimal place.

Q. 2.0. Did the odds ratio or the risk, did that change in any of these analysis?

A. No, Luix and Mitchell continued to report that the risk for a septal heart defect was doubled under women exposed to Zoloft.

Q. So the change at most was only in the lower bounds of the confidence interval from 1.2 to 1?

A. Correct. From 1.2 to 1.0.

Q. And in your big charts here that puts Luix septal right there, 2.0, 1.0 to 4.0, right?

A. Yeah, it's that one there that just touches the line because it's right at 1.0.

Q. So it used to be at 1.2 and that one line moved left?

A. It moved a very small amount to the right at the end of the confidence interval, just over 1 now.

Q. In this sea of information, Dr. Jewell, as you described it, did that -- first of all, were you happy to get that data and see it?

A. Absolutely. I think it's important to be correct and I'm glad that they published a correction and it was discovered. I think that was valuable and I hadn't noticed it and Dr. Kimel did. I think that was terrific. You gotta get the right data and that's what they claim the data showed.

Q. Did you bring that new data into your analysis?

A. I did.

Q. Did adding that one change in the lower bounds of that confidence interval change your ultimate opinion about whether or not Zoloft is causally associated with cardiac birth defects?

A. Well, it didn't ultimately not because it's

not important whether it clips the line or not, whatever you believe about significance. As I said, that would have been a big deal to me if it was the only study we were talking about, strip away everything else. But as you can see, this was a piece of information in other information about septal defects and septal defects, in and of themselves are already a subcategory where it's already hard to be precise. And so I was more focused on the all cardiac outcomes and then looking to see if there was consistency in what you see in all cardiac outcomes when you look at some outcomes. And of course, that confidence interval change didn't change my perception of is the information in Luix about septal heart defects consistent with what we see in general for all cardiac defects.

Q. Dr. Jewell, are any of the opinions that you've ever expressed professionally, so unstable that the change of a lower bounds of a single confidence interval in one of forty-five different outcomes by .2 that your opinion is so unstable that that one change in that sea of data would ever impact your ultimate conclusion?

A. Well, isn't that an incomplete hypothetical?

Q. Why? Objection, incomplete hypothetical.

The witness is objecting.

(Laughter)

THE WITNESS: I'd like the context first. I've already said in a single study where you've got a single primary end point knowing whether the results are significant seems to me to be quite important. And I think many people would agree with that. When you're dealing with a secondary end point and you have multiple studies of the same issue it becomes a piece of -- it's important to get it right, no question, but it only becomes a piece of a much bigger story as the plot indicates. And so it did have an impact on my opinion, but very, very slight and not enough, in any way, to change my substantive opinions at the end.

Q. So Dr. Jewell, let's talk about your charge in this case and your methodology. I've put up a slide here that you've seen before. Does this capture in sort of a summary fashion how you went about analyzing the question presented, which was is there a causal association between the use of Zoloft during pregnancy and cardiac birth defects?

A. I think you described it pretty well for a non-statistician.

Q. So in the first step of gathering the

relevant literature and extracting the data, in your report, these were what you called your eleven core studies. Is that right?

A. That is correct.

Q. And why did you define core studies in this fashion?

A. Well, as I indicated, I wanted to use peer review, published studies. I wanted to at least have some review of the data source having gone on by peer review. I wanted studies that were reporting about original data, not just rehashing a previous paper, I can look at the original data, so I didn't really want data just commentaries on other people's opinions. I wanted to make up my own mind.

I wanted papers which had specific results about Zoloft, not papers that talked about SSRIs in general. And specifically they had to give me results about Zoloft, even though they might have mentioned Zoloft in the article, that was one of the SSRIs. If they didn't give me data specifically to Zoloft, I didn't want to rely on a class effect or any other assumption.

And I wanted it for a specific outcome, which corresponded to the charge, which in this case was cardiovascular birth outcomes, not all congenital

abnormalities or I needed to have something of a cardiac effects. And these were the eleven studies that met each of these criteria.

Q. So for example, when you say with original data, the AHA paper that we saw earlier and summarizing two studies and reaching its conclusion, that's not something that you would have deemed a core piece of evidence for your analysis?

A. Did not provide the core data. I did look at those meta analysis later to see the insights of the authors and see if they shed light on the quality of the individual studies, but I did not individually use that to originally to come to my opinions.

Q. And when you say that it was Zoloft specific results, I believe there was only one paper that has Zoloft specific results as its entire paper and that's Dr. Berard's paper, but did most of these papers address other SSRIs and other anti-depressants?

A. I think actually all of them addressed other SSRIs, but they would provide data on Paxil and Zoloft broken down separately so they would be comparing women specifically exposed to Zoloft to women not exposed to any SSRI, so that's what I was looking for.

Q. And you mentioned the class fallacy or the class effect, what are your concerns now after this

review in particular and you've done, what concerns do you have about looking at data that covers all SSRIs and trying to reach a conclusion about Zoloft in particular?

A. Well, the trouble is the heterogeneity again that can arise that there might be different effects for different pharmaceuticals on the same outcome. And if you put them all in together you'll get an averaging which may not be accurate in describing any one of the drugs as we just talked about earlier. So I didn't want to get caught into that and then having to hypothesize and guess as to what extent the results for all SSRIs really reflect the actions of Zoloft. So I tried to avoid that entirely.

Q. And your choice to look at cardiovascular birth defect outcomes or all cardiac outcomes and any cardiac outcomes, was that a choice that was effectively mirrored in all of this literature?

A. I don't think there's been a single paper we've discussed today that has not looked at that category and that's where I took my information. Certainly all eleven of these do look at all cardiac outcomes.

Q. So we talked a little bit, Dr. Jewell, or I did in my opening about overlapping populations. Was

this a surprise to you or was this something that you specifically addressed in your report that some of these populations overlap?

A. No, it was immediate. As soon as you go to an in depth analysis of the papers and the first question you'll ask is where did the data come from, what is the population, who are the women, who are the children? You see that overlap very quickly. Some of the authors comment on the fact that they're updating or overlapping with preexisting papers, so I knew that almost from the minute I opened the papers, but of course became much more intimately familiar with the extent of the overlap as I looked at it in more detail.

Q. And why was that important for you, Dr. Jewell, to not just say, oh these are all from Denmark, I'm only going to take the latest one and throw the others out? Why did you instead do a more in depth look at whether or not they were actually similar or the same?

A. Well, there are two reasons for that. Two things you have to figure out. One is, if one study completely subsumes another, in other words it takes all the data that the first study has and adds more then there's a little bit less anxiousness about maybe

just using the more recent study. That's a little bit true of the Swedish studies, the Reese Colin and the Colin.

You might look in those situations, particularly if the recent data contradicts what the earlier data said or not. That's still worth doing and in fact, I did that on the extension of the Alwin paper that was discussed this morning. I specifically looked, okay we have new data now. Does it give the same odds or ratio as what we saw a few years ago when Alwin looked at the data. So that's worth it in itself just to see if things changing in time, population, what's going on here, is it replicating what the earlier results show or not.

The second issue is and there is the -- someone just slashed out the Swedish ones where it's contained, so you might look at the dark blue here and say well, we knew about the light blue when Colin did their data up to 2004, but does the dark blue, which has three more years of data, give different information or the same. And if it's the same, it won't change the odds ratio that much and that's what you can see here. So in fact, Reese did not break out the new data and provide that, but you can see from the odds ratio, they hardly change. So that means the

dark blue were not dramatically different. There was no head in the oven. If the green is cold, you know, there's no red there so very similar information.

And I did that for each of these cases. Now, it becomes much more important where there's less overlap in this case not complete overlap. The idea that Jimenez Solem and Carnum are just essentially saying the same thing, it's the same population, yes they're all Danish women and that's terrific because the Danish registry system is pretty good about reporting outcomes and reporting pharmaceutical exposures, but Carnum was just one part of Denmark. And so the natural question you might have thought of coming out of Carnum, maybe Carnum himself thought about this is can we replicate this in other parts of Denmark. Is there something particular about this part of Denmark? They didn't do that as far as I'm aware.

Peterson did sort of take the first natural step and said let's do all of Denmark, but because he was looking for specific exposure information, he had to limit -- he and his team had to limit their investigation to 1996 and later, so they couldn't cover exactly what Carnum did. And then now much later, Jimenez Solem, again using all of Denmark, the

registry data, looked at a much longer period of time. So there's a lot more information in Jimenez Solem than was in Peterson. That's important, there was more information, but it's also important to see about replication.

Peterson did this. He found, in this case it's odds ratio of 2.4, now you get some new data. The first question any statistician is going to think about is heterogeneity. Does the new data replicate what we saw before? That replication is the cornerstone of science. Does it replicate?

Well, Jimenez Solem doesn't actually break out the data. I would have loved to have done that. And then you could have a slide, here's what Peterson knew and here's the extra data that Jimenez Solem did. Do they look the same or not? But again, look at the odds ratios. If Jimenez Solem had an odds ratio of one for all that new data, that 2.36 in Peterson necessarily would have to drop enormously well below to down because Jimenez Solem is essentially almost double, even more Peterson. Averaging would have brought it way down.

Now, what do we see from Jimenez Solem? We see 2.7, so what does that tell us? It tells us that the new blue data, these are new women studied after

Peterson had been published, did they show the same effect? They not only showed the same effect, they had to show an even stronger effect for the entirety of Jimenez Solem to take the odds ratio up from 2.4 to 2.7.

I wasn't particularly driven by that difference between 2.4 and 2.7, because look at the confidence intervals. What is important and what people still seem to refuse to understand is that this provides a modicum of replication. These are new women, newly studied and they give the same, if not more extreme results in terms of the association. That replication is important.

Is it the only replication that's important? No. I now want to look at the U.S. data and the Finnish data and the whole set of studies, but that replication is important. So the overlapping is important to recognize, but also to exploit to understand whether that 2.3 had just been random because of a spurious association wouldn't it have disappeared in a new set of women at random? The answer, it didn't disappear and that's why replication is so important as compared to worrying about multiple comparisons within an individual study and that's what I discuss in my report, that distinction and that

replication trumps multiple comparisons.

Q. So you said, Dr. Jewell, that you also looked at it for the Alwin data and we looked at this earlier with Refuse (ph) being an update to Alwin and do you know Professor Brackin at Yale University School of Public Health?

A. I know of him. He's a very eminent, perinatal epidemiologist. I don't know him personally.

Q. And did you have an opportunity to review his comment about the strategy of using the subset of later data to compare to the earlier data to examine replication and chance?

A. Yeah. He had the same kind of reaction I did that I just tried to explain, maybe badly, but I just tried to explain why that's important to look at the new data. And if it gives you a completely different result, you then get very suspicious that this is just something spurious or chance.

Q. And then you applied that to the Alwin Refuse comparison. Is that right?

A. Correct.

Q. And when you ran the difference between the outcomes here as described by Dr. Brackin doing it, did you find that the newer data, the newer 8,000 plus

5,000 -- you're the mathematician.

A. Yeah, 14,000 yeah.

Q. That new data while it's reported as a 1.0 when it includes the Alwin data, that necessarily the new data that was not included in Alwin would have had a different affect?

A. Well here it was a little different from Jimenez Solem because they did provide in their supplement the ability to break out the data and see the new data and directly compare it. And the new data showed a stronger, not very strong, but a stronger association than originally in Alwin. This is just I think, this is not for all cardiac, this is just septal defects. And refuse was the only paper that I've seen that didn't actually talk about all cardiac and that's because Alwin didn't find it interesting and the original and they only focused on the results of the earlier paper in this case.

Q. So I put up there 1.2, 1.3, did you actually do that calculation at some point?

A. I did.

Q. And do recall what it was?

A. My memory is it's 1.22, but I hate to go by memory.

(Conclusion of requested transcript at 3:27 p.m.)

* * * * *

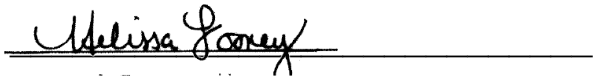
CERTIFICATIONS

I, Sheila G. Orms, certify that the foregoing is a correct transcript from the official electronic sound recording of the proceedings in the above-entitled matter.

Dated: July 9, 2015

Signature of Approved Transcriber

I, Melissa Looney, certify that the foregoing transcript is a true and accurate record of the proceedings.



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